

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
)	

**DEFENDANTS' OPPOSITION TO DEPUY MITEK'S MOTION FOR SUMMARY
JUDGMENT OF INFRINGEMENT AND NO INEQUITABLE CONDUCT**

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I. INTRODUCTION

Defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Ltd. (“Pearsalls”) (together, “defendants”) submit this Opposition to DePuy Mitek Inc.’s (DePuy Mitek”) Motion for Summary Judgment of Infringement and No Inequitable Conduct and Memorandum in Support Thereof (DM Mem.”). DePuy Mitek concedes, as it must, that it is not entitled to summary judgment unless the Court adopts its proposed claim interpretations. But DePuy Mitek conveniently forgets to tell the Court that, even under its theories, it is only seeking summary judgment if the Court rules in its favor on *both* of the contested claim construction issues. Should the Court rule in defendant’s favor on *either* of the disputed claim construction issues (“PE” or “consisting essentially of”), summary judgment cannot be granted for DePuy Mitek because, under DePuy Mitek’s view of the evidence, there would be a factual dispute as to whether the accused FiberWire products meet at least one limitation of each asserted claim.¹

As we show below, DePuy Mitek is not entitled to summary judgment even if the Court were to rule in DePuy Mitek’s favor on both of the contested claim interpretation issues. First, under any rational application of DePuy Mitek’s proposed interpretation of the basic and novel characteristics of the claimed invention, a coating, which is added to the FiberWire product, affects those basic and novel characteristics. Second, DePuy Mitek’s motion fails because it ignores several of defendants’ non-infringement defenses, namely, the addition of an adhesive that tips the FiberWire suture and defendants’ reverse doctrine of equivalents contention.

DePuy Mitek’s arguments in its inequitable conduct motion are equally as faulty. DePuy Mitek’s principal argument is based on its assertion that defendants’ inequitable conduct allegation is bottomed on nothing more than applicant’s “Arguing With the Patent Office About The Teachings of a Disclosed Reference.” DM Mem. at 21. DePuy Mitek’s premise is wrong.

¹ As we demonstrated in Defendants’ Memorandum in Support of Defendants Arthrex, Inc.’s and Pearsalls, Ltd.’s Motion for Summary Judgment (“Defendants’ SJ Mem.”), defendants believe that they are entitled to summary judgment should the Court rule in defendant’s favor on *either* of the two claim interpretation issues.

To the contrary, defendants' inequitable conduct claims are based on misrepresentations of fact made by Ethicon in the responses it filed to the examiner's rejections of the claims.

More specifically, the examiner rejected the then pending claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 1), explaining that it contained all limitations of the claims except that it was a fishing line instead of a suture. Ex. 2 at 4. In response, Ethicon stated that the combination disclosed in Burgess -- UHMWPE and polyester or nylon -- would, if used to make a suture, have poor knot strength properties and would inevitably lead to an unacceptable suture. Ex. 3 at 2-4. But inventor Steckel, at his deposition, testified precisely to the contrary, asserting that he and his co-inventor, Mr. Hunter (who is now deceased), believed that the combination of UHMWPE and PET (the polyester specifically mentioned in the claim)² would have good knot tying characteristics and would make a fine suture. Ex. 5 at 189:19-190:5. The principles of inequitable conduct prevent this exact type of two-faced behavior -- believing one thing, but telling the Patent Office the opposite in an effort to obtain a patent.³

II. COUNTERSTATEMENT OF FACTS

A more complete counterstatement of undisputed facts is included in Defendants' Memorandum in Support of their Motion for Summary Judgment, which is incorporated herein by reference. We point out here, however, that DePuy Mitek's factual presentation (DM Mem. at 2-4) leaves out most of the pertinent facts and that many of the "facts" presented in DePuy Mitek's memorandum are anything but undisputed.

DePuy Mitek makes only a single cite to the specification of the '446 patent. The reason for that omission is obvious -- a more complete discussion of the patent specification would

² As DePuy Mitek's expert Dr. Brookstein explained, PET and polyester are synonymous to those skilled in the art of suture. Ex. 4 at 54:4-6.

³ The inequitable conduct allegation in connection with Ethicon's response to a rejection based on the Kaplan reference also does not involve arguing with the Examiner over what was disclosed in the reference. Rather, it involves an amendment to the claim to avoid the citation of prior art and an intentional misrepresentation of Kaplan.

demonstrate that its arguments about “PE” and “consisting essentially of” do not make sense. Even the one citation to the specification that it chooses to include, where the specification states that “it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid” (DM Mem. at 2), is designed to mislead. Depuy Mitek would like the Court to believe that the ‘446 patent is merely about braiding together any two dissimilar fibers so that it can offer a broad and incorrect view of the basic and novel characteristics of the claimed invention. But the broad claims directed toward two dissimilar fibers were *abandoned* during prosecution. The *issued* claims were narrowed to a combination of very limited and specifically identified materials. Yet DePuy Mitek’s memorandum is silent about the contributions of the specific materials identified in the claims.

DePuy Mitek goes on to say that there is no dispute about the structure of Arthrex’s FiberWire (DM Mem. at 2), and boldly asserts that it is undisputed that the braided sheath of the FiberWire sutures contains “polyethylene (‘PE’).” *Id.* at 3. There is probably no fact more in dispute in this case. It is defendants’ position that FiberWire *does not* contain “polyethylene (‘PE’)” as that term “PE” is used in the ‘446 patent. And it comes as no surprise that DePuy Mitek simply ignores the fact that FiberWire also contains a coating in its “undisputed” description of the FiberWire structure.

DePuy Mitek is equally as fast and loose with its reference to Arthrex’s FiberWire patent. DM Mem. at 3. While the “drawings” are from the patent, the annotations added to the drawings in DePuy Mitek’s memorandum are entirely from DePuy Mitek. By omitting that “fact,” DePuy Mitek wants to leave the impression that the patent drawings label the UHMWPE material as “PE” when DePuy knows that is not the case.⁴

⁴ DePuy Mitek’s assertion that Pearsalls “exclusively manufactures and imports FiberWire bulk suture into the United States for Arthrex” is misleading. Pearsalls merely sends a braid to the U.S. that will later be made into suture by others. Ex. 6 at 32. Moreover, Pearsalls also makes fishing line which is made by braiding together UHMWPE and PET (Ex. 7), the same materials braided together to make FiberWire.

DePuy Mitek's assertion that "FiberWire's Development Mirrors the Teachings of Mitek's 446 Patent" (DM Mem. at 4) is argumentation based on misleading or incorrect facts. In fact, DePuy Mitek's assertion is backwards -- defendants' development of FiberWire is the *opposite* of the teachings of the '446 patent. Fundamentally, the '446 patent is about a suture with improved pliability and handleability characteristics without a significant sacrifice of strength. Ex. 8 at ¶ 56. FiberWire is the opposite; it is a high strength suture -- twice the strength of conventional sutures while maintaining sufficient handleability characteristics. Ex. 8 at ¶ 8.

In addition, the '446 patent teaches that the material from the "first set of yarns" is included to improve the handleability and pliability while the material from the "second set of yarns" is added to provide sufficient strength. Ex. 8 at ¶¶ 32, 33. Once again, FiberWire is the exact opposite. The material that Depuy Mitek contends is from the "first set of yarns" (UHMWPE) is added for strength, while the material from the second set of yarns (PET) is included for better handleability characteristics. Even DePuy Mitek's expert, Dr. Brookstein agreed with this description of FiberWire. Ex. 9 at ¶ 56.

The statements that DePuy Mitek ascribes to Don Grafton, one of the named inventors on the Arthrex patent for FiberWire (DM Mem. at 4), are misleading and inaccurate. Mr. Grafton, never testified that he made a braid of "PE." To the contrary, Mr. Grafton testified that he used UHMWPE (Ex. 10 at 45:10-46:9), a product that he knew to be incredibly strong (Ex. 10 at 45:19-20), a characteristic that could never apply to general purpose PE. Similarly, Mr. Grafton did not state that the UHMWPE braid suffered from poor strength. He explained, over and over again, that, in the configuration that was tested, the knot was slipping and was not secure. Ex. 10 at 45:10-46:9. This is a knot security issue, which is very different from knot strength. Ex. 10 at 25:4-15. Indeed, the '446 patent itself recognizes the difference between these two concepts, and

so did the DePuy Mitek and Ethicon witnesses when asked about these characteristics. Ex. 11 at col. 6, ll. 30-44, Table; Ex. 12 at 63:24-64:15, 73:12-16; Ex. 4 at 366:7-367:5.

III. DEPUY MITEK IS NOT ENTITLED TO SUMMARY JUDGMENT OF INFRINGEMENT

As explained above, DePuy Mitek's motion is predicated on this Court ruling in its favor on both of the contested claim interpretation issues. Accordingly, should the Court fail to adopt either or both of DePuy Mitek's proposed claim constructions, DePuy Mitek's motion must be denied. But even if the Court were to agree with DePuy Mitek's proposed interpretations, summary judgment is still not appropriate because (1) coating affects the basic and novel characteristics of the claimed invention even under DePuy Mitek's proposed interpretation of "consisting essentially of" and (2) DePuy Mitek fails to consider defendants' other non-infringement defenses.

As an initial matter, defendants do not contest that one of the materials in the FiberWire braid is UHMWPE. Defendants assert that this material is not "PE" as that term is used in the '446 patent and thus, DePuy Mitek's motion should be denied. We do believe, however, that DePuy Mitek's argumentation on this issue is inappropriate and is designed to confuse the record. DePuy Mitek asserts that "numerous Arthrex documents confirm that FiberWire is made of PE" (DM Mem. at 7), relying on two marketing documents that use the term "polyethylene." But DePuy Mitek knows that the claim interpretation issue is the meaning of "PE," as it is used in the '446 patent, to one of ordinary skill in the art in 1992 (when the patent application was filed). The answer to that dispositive question focuses primarily on the intrinsic evidence, the claims, specification and prosecution history of the '446 patents. Marketing documents written a *decade* later and which are completely divorced from the '446 patent are of no value and do nothing to aid the Court in deciding the real issues in the case.

A. Coating Affects The Basic And Novel Characteristics Of The Claimed Invention Under Depuy Mitek's Interpretation

While defendants vigorously disagree with DePuy Mitek's version of the basic and novel characteristics of the claimed invention (*see* Defendants Opposition to DePuy Mitek's Brief in Support of its Claim Construction of the Hunter Patent – U.S. Patent No. 5,314,446 (“Defendants’ *Markman* Opp.”) at 2-9), infringement is very much in dispute even if the Court were to adopt DePuy Mitek's interpretation. According to DePuy Mitek, the basic and novel characteristics are:

[A] heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

DM Mem. at 7.

Applying this definition, the coating on FiberWire still affects the basic and novel characteristics of the claimed invention. The DePuy Mitek proposal requires that the two dissimilar yarns have different properties that each contributes to the overall properties of the braid. Here, PET is one of the yarns of the FiberWire braid. As DePuy Mitek itself contends, one of the purposes of the PET is to improve the knot tying ability of the suture braid. *See* Ex. 13 at ¶ 15. As we demonstrated at length in Defendants’ Memorandum in Support of Their Motion for Summary Judgment (at 14-15), this is one of the undisputed and long-known reasons for coating a suture. Accordingly, even under DePuy Mitek's view of the basic and novel characteristics of the claimed invention, coating has a material affect on the property that PET brings to the braid and its inclusion in FiberWire precludes a finding of infringement.

Perhaps recognizing the problem with its position, DePuy Mitek offers a bizarre manner of implementing how an added material can affect the basic and novel characteristic of an invention. Relying upon its report of its expert, Dr. Brookstein, DePuy Mitek argues that the coating does not affect the basic and novel characteristics of the claimed invention because

“FiberWire still has a heterogeneous braid of dissimilar materials in direct intertwining contact where the dissimilar yarns contribute different properties to the braid.” DM Mem. at 8. But when asked at his deposition how a coating could materially affect the basic and novel characteristics under this test, Dr. Brookstein responded that coating could only affect the basic and novel characteristics if “the coating in some *miraculous* way made those materials not yarns anymore” or “all of a sudden you had a set from A, a set from B and now it was some magical structure that wasn’t yarns, it wasn’t two sets, they were all the same, that would be a transformation.” Ex. 4 at 398:18-400:15. [Emphasis added.] According to DePuy Mitek, only “magic” and “miracles” can cause an added material to affect the basic and novel characteristics of an invention. It comes as no surprise that Depuy Mitek cites no law for this astonishing proposition. It cannot because the only requirement of the law for an effect to be material is that it be of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.* 156 F.3d 1351, 1354 (Fed. Cir. 1998).

DePuy Mitek’s argument is that the coating, or any other substance, would have to operate in such a way that there is no longer direct intertwining contact between the two sets of yarns or that the two dissimilar materials were transformed so that they are no longer different materials. But this is the same thing as saying that there is no infringement because the accused device no longer meets one of the stated limitations of the claim. But infringement of a “consisting essentially of” claim also requires proof that the added substance does not materially affect the basic and novel characteristics. If that requirement could *only* be met by showing that the accused device no longer has one of the identified limitations, then the added requirement for a “consisting essentially of” claim would be meaningless. That is not, and cannot be the law.⁵

⁵ DePuy Mitek offers the same bizarre application of its “basic and novel characteristics” to contend that the addition of nylon to TigerWire does not avoid infringement under its interpretation of the basic and novel characteristics. DM Mem. at 8-15. And for the same reasons discussed above, DePuy Mitek’s argument fails. The simple fact is that the addition of nylon affects both the strength and the pliability of the suture. Ex. 6 at 30-31.

B. Depuy Mitek Ignores Defendants' Other Infringement Defenses

A plaintiff's summary judgment motion must show that there are no genuine issues of material fact on any non-infringement defense raised by the accused infringer. *See, e.g., TechSearch, L.L.C. v. Intel Corp.*, 286 F.2d 1360, 1369 (Fed. Cir. 2002) (moving party is entitled to summary judgment only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact"). DePuy Mitek's motion focuses only on the "PE" and coating issues and ignores the other non-infringement defenses raised by defendants in their interrogatory answers. DePuy Mitek's failure to consider these defenses is another reason that its motion should be denied.

For example, defendants, in their interrogatory answers, explain that the ends of the FiberWire suture are tipped (*i.e.*, stiffened) by approximately 1 inch by adding an adhesive material to the suture during processing. Defendants explain that tipping the ends improves handleability because it makes it easier for surgeons to thread the suture through surgical instruments, prevents fraying of the ends, serves to restrict the fiber mobility of the two dissimilar materials and restricts the bendability, *i.e.*, pliability, of the tipped portion of the suture. Ex. 14 at 9-10; Ex. 15 at 9-10.

Defendants also raise a defense of no infringement under the reverse doctrine of equivalents. Ex. 14 at 5; Ex. 15 at 5. Under that doctrine, there is no infringement "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim." *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.2d 1357, 1368 (Fed. Cir. 2002) (citing *Graver Tank & Manufacturing Co. v. Linde Air Products, Co.*, 339 U.S. 605, 609 (1950)). The reverse doctrine of equivalents raises a fact question -- whether a product has been so far changed in principle that it performs in a substantially different way -- and summary judgment should not be granted if the accused party raised a factual issue as to whether

the doctrine applies. *See, e.g., SRI Intern. v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1124-25 (Fed. Cir. 1985).

Defendants, of course, believe that there is no infringement, but if the fact finder were to conclude that the FiberWire product technically meets the limitations of the claims, it would do so only by operating in a dramatically different way from that described in the ‘446 patent. The ‘446 patent teaches that the first set of yarns contributes pliability and handleability characteristics to the braid and the second set provides added strength. FiberWire is exactly the opposite. Moreover, the ‘446 patent teaches improved handleability by combining the two dissimilar materials. FiberWire does not operate that way. It needs a coating to achieve those results. Ex. 14 at 4-5; Ex. 15 at 4-5. Accordingly, the reverse doctrine of equivalents is at issue and precludes summary judgment.

IV. DEPUY MITEK IS NOT ENTITLED TO SUMMARY JUDGMENT DISMISSING DEFENDANTS’ INEQUITABLE CONDUCT ASSERTIONS

A. The Law Of Inequitable Conduct

Patent applicants and those substantively involved in the preparation or prosecution of a patent application owe a “duty of candor and good faith” to the PTO. 37 C.F.R. § 1.56(a) (2004); *see also, Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Examiners expect and rely on inventors and their attorneys or agents to be truthful and to act with candor and good faith in dealing with the PTO. The duty applies to all individuals associated with the filing or prosecution of an application. These individuals have a duty to disclose information known to one or more of them to be material to patentability. *See* Ex. 16 at ¶ 28.

“Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of ‘candor, good faith and honesty.’” *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1342 (Fed. Cir. 2005) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). A breach of this duty, when coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct and renders the patent unenforceable. *Liquid Dynamics, Corp. v. Vaughan, Co., Inc.*, 449 F.3d 1209, 1226 (Fed. Cir. 2006).

Proof of inequitable conduct in the prosecution of a patent requires evidence of an affirmative misrepresentation of a material fact, coupled with an intent to deceive. *See, e.g., NovoNordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005). Information is material when it is not cumulative to information already of record and it is inconsistent with a position the applicant takes in either opposing an argument of unpatentability or asserting an argument of patentability. Ex. 16 at ¶ 30.

Intent need not be proven by direct evidence. *See Merck & Co., Inc. v. Danbury Pharm. Inc.*, 873 F.2d 1418 (Fed. Cir. 1989). Intent is generally inferred from the facts and circumstances surrounding the applicant's overall conduct. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005). In proving intent, proof of deliberate scheming is unnecessary, gross negligence may constitute sufficient wrongful intent to support a holding of inequitable conduct. *See Reactive Metals & Alloys Corp. v. ESM Inc.*, 769 F.2d 1578, 1583-84 (Fed. Cir. 1985).

B. Defendants' Inequitable Conduct Allegations Are Not Based On A Disagreement Between The Examiner And The Applicant About The Teaching Of Disclosed References

DePuy Mitek's principal argument seems to be that there can be no inequitable conduct because defendants' allegations amount only to an assertion that the applicant and the examiner were "merely arguing . . . about the teachings of a disclosed reference." DM Mem. at 21. But in making this argument, DePuy Mitek simply states that the references (Burgess and Kaplan) were before the Patent Office and then assumes, *without any record support*, that the proceedings before the Patent Office in connection with these two references only concerned a debate between the applicant and the examiner over the teachings of those references.

As a review of the record shows, defendants' inequitable conduct claim has nothing to do with such a disagreement. We begin first with the Burgess reference. The parties agree that the examiner initially rejected the claims based on the Burgess U.K. patent application that disclosed a braided fishing line made of UHMWPE and polyester or nylon. In responding, however,

Ethicon did not disagree with this characterization. Instead, Ethicon made a series of factual statements about the attributes of the braided combination disclosed in Burgess (UHMWPE and polyester or nylon) and why that combination would make a poor suture. Ethicon told the examiner that such a combination “would have poor knot strength properties because of its braided construction,” that the requirements for a fishing line would “yield a braid with poor knot strength and security” and that if one were to make a suture following the Burgess teachings, the designer “would inevitably design an unacceptable suture.” Ex. 3 at 2-4. These statements of fact -- what would happen to a suture braid made by the teachings of Burgess -- have nothing to do with a debate over what is disclosed in Burgess. They are statements of fact that are the *exact opposite* of the stated beliefs of inventor Steckel, who testified that during development, he and co-inventor Hunter believed a suture made of UHMWPE and polyester (the Burgess braid combination) could have improved knot strength properties and was a good idea that could lead to an acceptable suture.

This is the classic case of inequitable conduct -- believing one set of facts, telling the Patent Office a different story. *See, e.g., Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1371 (Fed. Cir. 2003) (finding that inventor committed inequitable conduct in responding to Office Action by making material misrepresentations known to be untrue regarding purification protocol); *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000) (finding inequitable conduct where patentee made affirmative misrepresentation to the examiner regarding the filing date application was entitled to when he knew board reached a contrary result); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (finding inequitable conduct where patentee submitted false affidavit to overcome prior art rejection). It is not “merely arguing” with the Patent Office about the teachings of a disclosed reference.

Turning to Kaplan, DePuy Mitek would like the Court to believe that this is a garden variety situation where the examiner issued a rejection based on a reference, explained why the reference supports the rejection and then the applicant explains why the examiner’s interpretation

of the reference is incorrect. But here, the applicant did *not* argue with the examiner's interpretation of the Kaplan reference and never expressed *any* disagreement with the examiner's reasoning. Rather, the applicant narrowed the claims by amendment and then argued that Kaplan no longer applied. In support of its argument, Ethicon made new arguments about the Kaplan reference never mentioned by the examiner, and which intentionally mislead the examiner about what was taught by Kaplan. In short, there was never any "debate" or "argument" with the examiner about what was disclosed by Kaplan. The inequitable conduct involves applicant's intentional misstatements and the examiner's reliance on these misstatements in deciding to allow the patent.

C. Ethicon Committed Inequitable Conduct In Connection With The Burgess Reference

As explained above, inventor Steckel testified that, at the beginning of the development work that lead to the '446 patent, he and inventor Hunter considered a braided combination of UHMWPE and PET polyester – the same braided combination disclosed in Burgess – and believed that such a combination would have improved knot strength and would make an acceptable suture.⁶ These beliefs by the inventors, which were never disclosed to the Patent Office, are diametrically opposite to the position taken by Ethicon when responding to the rejection based on Burgess. As explained above, Ethicon asserted in its response that the Burgess braid would have "poor knot strength and security" and that a suture designer following the Burgess teachings "would inevitably design an unacceptable suture." Ex. 3 at 2-4. [Emphasis in original.]

There is no question that these misrepresentations were highly material because, as defendants' expert Mr. Witherspoon explained, they were made in a successful attempt to

⁶ We recognize the distinct possibility that Dr. Steckel was not testifying truthfully because he and DePuy Mitek had every incentive to try to create the illusion that Ethicon had UHMWPE in mind as it was performing the work that led to the '446 patent. The record casts serious doubt on Dr. Steckel's testimony because there is no written corroboration of Dr. Steckel's testimony and the '446 patent describes "PE" as weak and pliable, contrary to the attributes of UHMWPE, which is strong and stiff. Ex. 11 at col. 2, ll. 22-25; Ex. 9 at ¶ 56; Ex. 17 at 306:20-307:4.

overcome a rejection based on very close prior art. Ex. 18 at ¶ 8. *Rohm & Haas*, 722 F.2d at 1571-72. Even DePuy Mitek does not contest that these representations were material. They cannot, as Ethicon acknowledged to the Patent Office that the Burgess rejection was withdrawn based on Ethicon's arguments. Ex. 19 at 7-8.

Instead, DePuy Mitek argues that there was no inconsistency between Dr. Steckel's testimony and Ethicon's statements to the Patent Office because Dr. Steckel was testifying about suture development while Ethicon's response to the Patent Office is about fishing lines. DePuy Mitek's argument is nothing but sophistry designed to confuse a very straightforward record. The simple and undeniable fact is that Ethicon's response concerned the properties of a braid made of UHMWPE and polyester – the same components about which Dr. Steckel was speaking.

A simple reading of Ethicon's misrepresentations leaves no doubt. First, Ethicon said that the "fishing line of Burgess would have poor knot strength properties because of its braided construction." Ex. 3 at 2. [Emphasis in original.]. The fishing line of Burgess *is* a braid of UHMWPE and polyester. Ethicon said that "the property requirements for fishing line *yield a braid with poor knot strength and security.*" Ex. 3 at 3. [Emphasis added.] Again, Ethicon said that the *braid* -- UHMWPE and polyester -- would have poor knot strength and security. Finally, Ethicon said that if a medical designer "did use the teachings of the fishing line art to modify a suture then he would inevitably design an unacceptable suture." Ex. 3 at 3-4. Once again, the fishing art from which Ethicon was trying to distinguish its invention was the Burgess braid of UHMWPE and polyester. The only rational interpretation is that Ethicon was telling the Patent Office that if a medical designer modified the Burgess braid into a suture, "he would inevitably design an unacceptable suture." "Ex. 16 at ¶ 61; Ex. 18 at ¶ 9. This, of course, is the opposite of Dr. Steckel's testimony.⁷

⁷ DePuy Mitek grossly misstates Mr. Witherspoon's testimony (DM Mem. at 26) in an attempt to create the impression that Mr. Witherspoon wavered on his opinion that there was a material misrepresentation. That is not so. Mr. Witherspoon, in his reports and at his deposition, expressed no doubt that the representations were material. Ex. 16 at ¶ 63; Ex. 20 at 137:25-139:21. Mr. Witherspoon explained that he used the phrase "may have been a violation" because

As explained above, the intent element is satisfied with proof of an intent to deceive the Patent Office or gross negligence. *See supra* at 11. There is plainly enough evidence of intent to defeat a motion for summary judgment. DePuy Mitek's argument that there was no intent amounts to little more than pointing to Dr. Steckel's and the prosecuting attorneys' denials of doing anything wrong. DM Mem. at 27. But intent is rarely proven through direct evidence; it is the rare case where the participant admits to the deception. *Bruno Indep. Living Aids, Inc.*, 394 F.3d at 1354. Rather, as here, the intent evidence needs to be determined from a consideration of all the circumstances. *Id.*

The evidence here shows that the inventors believed one thing, but Ethicon said the exact *opposite* in a successful effort to convince the Patent Office to grant a patent. It is that precise duplicity -- believing one thing, but stating the opposite to the Patent Office -- that the inequitable conduct doctrine is designed to punish. *See, e.g., Hoffman-La Roche, Inc.*, 323 F.3d at 1371. But that is not all. Mr. Goodwin, the attorney who submitted that Burgess response testified that Dr. Steckel was his principal contact in preparing and prosecuting this patent application. Ex. 21 at 75:8-76:7. It is simply not rational to believe that Dr. Steckel's views on such an important issue would be ignored or somehow overlooked. At a bare minimum, it would be grossly negligent to do so. *Reactive Metals & Alloys Corp.*, 769 F.2d at 1583-84. Moreover, we know from the privilege log that Ethicon apparently received comments for Ethicon's response to the Office Action at least from inventor Hunter (Ex. 22 at Tab 58) who, according to Dr. Steckel, was privy to the discussions about the alleged benefits of a braid made of UHMWPE and polyester. Ex. 5 at 189:13-24. This is still further evidence that there was an intent to deceive the Patent Office.

Intent, by its nature, is a fact laden inquiry that must be deduced from the circumstances. It is rarely the type of issue that can be decided on summary judgment. *Ferring B.V. v. Barr*

he had not seen direct evidence of a knowledge train from Dr. Steckel to Mr. Goodwin. Ex. 20 at 184:13-185:20. But Mr. Witherspoon went on to explain that there was circumstantial evidence that Dr. Steckel knew what the patent examiner was told and that there was evidence to infer what they knew. Ex. 20 at 185:6-8, 18-20.

Laboratories, Inc., 437 F.3d. 1181, 1204 (Fed. Cir. 2006) (stating “as a general rule, the factual question of intent is particularly unsuited to disposition on summary judgment”). This case is no different. There is an abundance of evidence from which the fact finder can rightfully conclude that Ethicon acted with the intent to deceive or with gross negligence. Accordingly, summary judgment should be denied.⁸

D. Ethicon Committed Inequitable Conduct In Connection With The Kaplan Reference

DePuy Mitek correctly observes that defendants’ contend that Ethicon committed inequitable conduct because it told the Patent Office that the sheath yarn component always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. DM Mem. at 22. DePuy Mitek does not dispute that Ethicon in fact made these representations to the Patent Office in response to a rejection based on the Kaplan reference. Likewise, DePuy Mitek does not dispute that, as a result of Ethicon’s representations, the examiner withdrew the rejection leading to the issuance of the patent. In other words, Ethicon does not dispute that the statements were material. *See Rohm & Haas*, 722 F.2d at 1571-72.

The sole argument advanced by DePuy Mitek on the materiality prong of inequitable conduct is that the representations Ethicon made about Kaplan were correct. It strains credibility that DePuy Mitek could contend that there is no disputed fact. Kaplan *twice* teaches that the sheath may, in some circumstances, only include non-absorbable material. In the summary of the invention, Kaplan explains that the sheath yarn can be formed from the same material as the core yarn. The core yarn is described as non-bioabsorbable. Obviously, if the sheath is made of

⁸ DePuy Mitek’s contention that defendants did not plead intent in their Answers or provide any evidence of intent in their interrogatory answers (DM Mem. at 27) is not correct. The Answers and Interrogatory responses identified the misstatements and alleged that intent was present because they could not have truthfully made these statements to the Patent Office if they believed that UHMWPE fell within their claimed invention and because they knew that the Patent Office would rely on the statements in reconsidering the rejections based on Burgess. Ex. 23 at 3-4; Ex. 24 at 4; Ex. 14 at 18-20; Ex. 15 at 18-20.

the same material, it also can be all non-bioabsorbable. Ex. 25 at col. 2, ll. 55-56, 59-61. Second, in the detailed discussion of the invention, Kaplan states that the “[s]heath yarn component may also be fabricated from individual filaments having more than two different chemical compositions, *one or more* of which optionally being nonbioabsorbable.” Ex. 25 at col. 9, ll. 25-28.] [Emphasis added]. A disclosure that “one or more” of the components can be non-absorbable must include, as a disclosed possibility, that all of the components are non-absorbable.

Once again, DePuy Mitek argues that there is not intent simply because the prosecuting attorneys and the inventors denied any wrongdoing. DM Mem. at 24. As explained above, that is the wrong standard; intent to deceive or gross negligence can, and usually is, inferred from the surrounding circumstances rather than a direct admission from the wrongdoer. *See supra* at 11.⁹ Here, Mr. Woodrow, who submitted the false statements, must have read the summary of the invention because he pointed to the summary to support his position. Ex. 26 at 159:15-20. Having done so, he must have known that Kaplan discloses a sheath made of only non-absorbable materials and that his assertion to the contrary is not accurate.

Second, in his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only non-absorbable materials. Ex. 27 at 2 [citing to Kaplan at col. 9, ll. 25-27]. But instead of *quoting* the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath “could *also* contain a non-absorbable yarn.” Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the non-absorbable component is merely added to preexisting absorbable components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false impression. Mr. Woodrow’s action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Ex. 19 at 6. But this time, when it did not matter

⁹ DePuy Mitek’s contention that defendants did not plead intent in their Answers is wrong. Ex. 23 at 3-4; Ex. 24 at 4.

(because the issue under consideration had nothing to do with the absorbable/non-absorbable matter), Ethicon *quoted* the sentence accurately. *Id.* Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent. Such are the actions of a person wanting to deceive.

V. CONCLUSION

For all the foregoing reasons, DePuy Mitek's motion should be denied.

Dated: September 1, 2006

Respectfully submitted,

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Counsel for Defendants
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants' Opposition to DePuy Mitek's Motion for Summary Judgment of Infringement and No Inequitable Conduct was served, via the Court's email notification system on the following counsel for Plaintiff on the 1st day of September 2006:

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EXHIBIT 1

(12) UK Patent Application (19) GB (11) 2 218 312 A (13)

(43) Date of A publication 15.11.1988

(21) Application No 8911088.8

(22) Date of filing 15.05.1988

(30) Priority data

(31) 8811498

(32) 14.05.1988

(33) GB

(51) INT CL

A01K 91/00, D04C 1/12

(52) UK CL (Edition J)

A1A A19

D1K K14

U18 81022

(56) Documents cited

None

(58) Field of search

UK CL (Edition J) A1A, D1K

INT CL' A01K, D04C

(71) Applicant

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(74) Agent and/or Address for Service

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Glamorgan, CF1 2AB, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

2218512

-1-

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

-1-

-2-

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple
5 and smooth sheath of polyurethane and this may
be carried out by a simple immersion process in
liquid polyurethane. It will alter the
characteristics (such as buoyancy and strength)
in a predictable manner, but its main purpose is
10 to prevent saturation of the interstices of the
braid. In very cold conditions, such as fishing
through holes in ice, water having worked its
way into the braid will freeze and impart a
brittleness that can lead to breakage.

SL/SCS

-2-

-3-

CLAIMS

1. A fishing line of braided construction,
some braid filaments being of high tenaxile polythene
thread and other filaments being of polyester and/or
nylon.
- 5 2. A line as claimed in Claim 1,, wherein
the other filaments include polyester multi-filaments.
3. A line as claimed in Claim 1 or 2, wherein
the other filaments include nylon monofilaments.
- 4... A line as claimed in Claim 1., 2 or 3, wherein
10 the braid is coated by a sheath of polyurethane.
5. A line as claimed in any preceeding Claim,
wherein the polythene is that sold under the Trade Mark
DYNEEMA.

-3-

Published 1989 at The Patent Office, State House, 66/71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office.
Sales Branch, St Mary Cray, Orpington, Kent BR5 3RD. Printed by Multiplex Techniques Ltd, St Mary Cray, Kent, Con. 1/87

EXHIBIT 2

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark OfficeAddress: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER	A ETH-782

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER RAYMOND C	
ART UNIT 1504	PAPER NUMBER 3

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 24 are pending in the application.
Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000186

Serial No. 838,511

-2-

Art Unit 1504

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

Serial No. 838,511

-3-

Art Unit 1504

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Serial No. 838,511

-4-

Art Unit 1504

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line—strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

Serial No. 838,511

-5-


Art Unit 1504

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclose a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.


Chris Raimund:jp
July 06, 1992



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000190

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

EXHIBIT 3



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 ✓

Art Unit: 1504

Filed : February 19, 1992 ✓

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

August 6, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

RECEIVED
AUG 17 1992
GROUP 150

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000194

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and, in turn, poor knot strength properties. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a


suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
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(908) 524-2791
August 6, 1992

EXHIBIT 4

Confidential Videotaped Deposition of:
Dr. David S. Brookstein, Vol. I

July 26, 2006

Page 1

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3 C.A. NO. 04-12457 PBS

4 _____ x
5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.
12 _____ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18
19
20 Reported by:

21
22 PAMELA HARRISON, RMR, CRR, CSR
23
24
25

		Page 54
1	of the question.	08:59:18a
2	THE WITNESS: I have no --	08:59:19a
3	BY MR. SABER:	08:59:20a
4	Q. Is it PET?	08:59:20a
5	A. PET and polyester are used	08:59:21a
6	interchangeably, yes. The polyethylene	08:59:23a
7	terephthlate is the official chemical name for	08:59:28a
8	polyester. Polyester is essentially a shorthand	08:59:32a
9	way of referring to polyethylene terephthlate.	08:59:36a
10	Q. Okay.	08:59:40a
11	A. Whenever you see those terms, they're	08:59:41a
12	the same thing.	08:59:42a
13	Q. Polyester, or...?	08:59:43a
14	A. Polyester and polyethylene	08:59:43a
15	terephthlate, T-E-R-E-P-T-H-L-A-T-E, and polyester	08:59:51a
16	are used interchangeably, in the literature, in	09:00:00a
17	the science, in teaching, by everybody.	09:00:03a
18	Q. Okay. And poly -- I have a little	09:00:09a
19	trouble with this --	09:00:12a
20	A. Okay.	09:00:15a
21	Q. -- polyethylene terephthlate --	09:00:15a
22	A. Terephthlate.	09:00:16a
23	Q. -- is referred to as PET?	09:00:16a
24	A. That is correct.	09:00:17a
25	Q. The -- could you -- I just want to tie	09:00:19a

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Dr. David S. Brrokstein, Vol. II

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Page 339

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

ORIGINAL

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13

14 DAY 2 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 27, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

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Dr. David S. Brokstein, Vol. II

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1	material will break.	Page 365 09:33:54a
2	Q. Yeah. And we're talking about on a	09:33:54a
3	tensile strength, do you have an understanding	09:33:56a
4	that that's testing that criteria with no knot in	09:33:57a
5	the material?	09:33:59a
6	A. On this chart, yes.	09:34:01a
7	Q. Okay. Now, the next column where it	09:34:02a
8	says knot strength --	09:34:04a
9	A. Yes.	09:34:05a
10	Q. -- do you have an understanding what	09:34:06a
11	that is, what that's -- what kind of test that's	09:34:07a
12	reporting?	09:34:12a
13	A. I have an understanding, yes.	09:34:12a
14	Q. What kind of test is that?	09:34:14a
15	A. That would be a test where one would	09:34:15a
16	tie a knot and then put it between two jaws, pull	09:34:17a
17	it apart, and see where it failed.	09:34:21a
18	Q. And you're testing where it would	09:34:23a
19	break at the knot; is that what it's testing?	09:34:25a
20	A. It doesn't necessarily mean it's going	09:34:28a
21	to break at the knot, but generally it does, yes.	09:34:30a
22	Q. Now, the knot strength test --	09:34:32a
23	A. Yes.	09:34:34a
24	Q. -- is that the kind of test -- I	09:34:35a
25	understand the procedures may be different.	09:34:38a

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		Page 366
1	A. Yes.	09:34:40a
2	Q. -- but the kind of test that you're	09:34:40a
3	referring to in your report when you use knot	09:34:42a
4	pull strength?	09:34:44a
5	A. Yes.	09:34:45a
6	Q. Okay. Now, the next category in the	09:34:46a
7	chart where it says -- excuse me; the last	09:34:49a
8	category where it says knot stability?	09:34:53a
9	A. Yes.	09:34:57a
10	Q. Do you understand that to be a knot	09:34:57a
11	security test?	09:34:59a
12	A. I have to go back and look.	09:35:00a
13	Q. Yeah, if you could -- if you want to	09:35:02a
14	go back to Column 6, I think that's where they	09:35:03a
15	start to talk about it.	09:35:05a
16	A. (Witness reviewing document.)	09:35:06a
17	Can you repeat your question?	09:35:35a
18	MR. SABER: Can you read it	09:35:36a
19	back, please.	09:35:37a
20	(The court reporter read the	09:35:37a
21	record as follows:	09:35:37a
22	"QUESTION: Do you understand	09:35:37a
23	that to be a knot security test?")	09:35:37a
24	THE WITNESS: The patent on	09:35:55a
25	number six talks -- says knot security; the	09:35:57a

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		Page 398
1	Q. All right. You have a sentence near	10:22:55a
2	the bottom of Page 15 --	10:22:59a
3	A. Page 15 or Paragraph --	10:23:01a
4	Q. Page 15. Page 15.	10:23:02a
5	A. Page 15, oh, okay.	10:23:04a
6	Q. Right. Which is in Paragraph 27.	10:23:05a
7	A. That's not what you said, you said	10:23:07a
8	Paragraph 15 originally, but fine.	10:23:09a
9	Q. Okay, I'm sorry.	10:23:10a
10	You say, In other words, the	10:23:12a
11	coating did not transform the braided	10:23:14a
12	FiberWire materials into another structure or	10:23:17a
13	cause it to lose its characteristics that are	10:23:21a
14	attributable to the dissimilar yarns being	10:23:24a
15	braided.	10:23:27a
16	Do you see that sentence, sir?	10:23:29a
17	A. I see that sentence.	10:23:30a
18	Q. Is it your opinion that to affect the	10:23:31a
19	basic and novel characteristics of the invention	10:23:36a
20	as Dr. Mukherjee describes them, that the coating	10:23:40a
21	would have to transform the braided FiberWire	10:23:44a
22	materials into another structure or cause the	10:23:48a
23	braided FiberWire materials to lose its	10:23:52a
24	characteristics that are attributable to the	10:23:56a
25	dissimilar yarns being braided?	10:23:58a

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		Page 399
1	A. It is my opinion that if the coating	10:24:09a
2	in some miraculous way made those materials not	10:24:11a
3	yarns anymore and they were no -- they were not	10:24:15a
4	dissimilar anymore, that that would be a change.	10:24:17a
5	If all of a sudden what was once a set of two	10:24:22a
6	dissimilar yarns miraculously became, for	10:24:26a
7	instance, a monofilament, that would be a change,	10:24:29a
8	yeah.	10:24:31a
9	Q. And that would affect the basic and	10:24:32a
10	novel characteristics?	10:24:33a
11	A. If the basic and novel characteristics	10:24:34a
12	are two dissimilar yarns, yes, and all of a	10:24:35a
13	sudden there weren't yarns in there anymore, it	10:24:38a
14	was some new material that was -- that we don't	10:24:41a
15	know about.	10:24:43a
16	Q. Or the yarns were the same yarns, made	10:24:44a
17	the yarns into the same yarns?	10:24:46a
18	A. If they were not dissimilar, right.	10:24:48a
19	Q. Right. So is it your opinion that if	10:24:49a
20	the coating does not -- does not achieve the goal	10:24:54a
21	that you just described, then it does not affect	10:25:00a
22	the basic and novel characteristics of the	10:25:02a
23	invention as Dr. Mukherjee defines it?	10:25:05a
24	A. Can you repeat the question.	10:25:07a
25	Q. Yeah, let me try and rephrase it.	10:25:08a

Deposition of:
Dr. David S. Brrokstein, Vol. II

July 27, 2006

		Page 400
1	Is it your opinion that the	10:25:12a
2	coating -- if the coating does not transform	10:25:15a
3	the braided material into another structure,	10:25:20a
4	would you -- let me ask it this way. What do	10:25:24a
5	you mean when you say transform the braided	10:25:27a
6	FiberWire materials into another structure?	10:25:30a
7	A. What do I mean?	10:25:32a
8	Q. Yes.	10:25:33a
9	A. I mean it's not dissimilar yarns	10:25:34a
10	anymore, that would be an example of what I	10:25:36a
11	mean. That all of a sudden you had a set from A,	10:25:38a
12	a set from B and now it was some magical	10:25:41a
13	structure that wasn't yarns, it wasn't two sets,	10:25:45a
14	they were all the same, that would be a	10:25:48a
15	transformation.	10:25:50a
16	Q. Okay.	10:25:52a
17	A. It would be alchemy, but it would be a	10:25:52a
18	transformation.	10:25:56a
19	Q. Okay. If that transformation doesn't	10:25:56a
20	occur by the coating, then is it your opinion	10:25:58a
21	that the coating doesn't affect the basic and	10:26:01a
22	novel characteristics of the invention?	10:26:02a
23	MR. BONELLA: Objection.	10:26:04a
24	THE WITNESS: That's not what I	10:26:04a
25	said.	10:26:05a

EXHIBIT 5

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

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DEPOSITION of DR. MARK G. STECKEL,
called as a witness by and on behalf of the
Defendant, pursuant to the applicable provisions of
the Federal Rules of Civil Procedure, before P.
Jodi Ohnemus, Notary Public, Certified Shorthand
Reporter, Certified Realtime Reporter, and
Registered Merit Reporter, within and for the
Commonwealth of Massachusetts, at the Courtyard
Marriott, 423 Speen Street, Natick, Massachusetts,
on Thursday, 26 January, 2006, commencing at 10:44
a.m.

1 Q. Would that include PET?

2 A. It would include, essentially, all of the
3 current -- all of Ethicon's non-absorbable
4 multifilaments at the time, which would include
5 PET, nylon, silk -- that's it.

6 Q. So, if I understand your testimony --

7 A. Yes.

8 Q. -- you had, at least in your mind --

9 A. Yes.

10 Q. -- the idea of braiding together Dyneema
11 and PET.

12 A. It was one of the combinations, yes.

13 Q. And did you have a view -- and when did
14 you have this idea?

15 A. This -- this would date back to the early
16 conversation with Al Hunter in terms of what
17 benefits could we derive from forming composites of
18 dissimilar fibers.

19 Q. Did you have -- in formulating this idea,
20 did you have any sort of belief that if you put
21 Dyneema together with PET, it would lead to an
22 acceptable suture?

23 A. It would lead to a suture with potentially
24 improved properties over Ethibond.

25 Q. Did you have a belief as to whether that

1 **would be an acceptable suture?**

2 MR. BONELLA: Objection. Asked and
3 answered.

4 A. We had a belief that it could lead to --
5 as you're saying -- an acceptable suture. There
6 were other issues that we didn't know. For
7 example, how the -- how polyethylene behaved in the
8 body. So, it was a high priority. Polyethylene,
9 even though there was an interest, it wasn't a --
10 it wasn't something that was a high priority at the
11 time.

12 **Q. The thought didn't cross your mind that,**
13 **Oh, this would make an unacceptable suture to put**
14 **Dyneema together with PET?**

15 A. My recollection was -- an unacceptable
16 suture or an acceptable?

17 **Q. An unacceptable suture.**

18 A. Well, the concern with any of the very
19 high-strength fibers was always knot strength, and
20 that was true whether it was Dyneema, Spectra,
21 Kevlar, etcetera. So, the general view was, I
22 mean, all of those -- 100 percent, all of those,
23 Ethicon evaluated at one point as a suture
24 material. They're the world's biggest suture
25 material company. And all of them there was an

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446
AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

In response to the rejection based on the Burgess application, Ethicon's attorney recognized that UHMWPE had great strength properties, but argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application – then “he would inevitably design an unacceptable suture,” (Ex. 5 at 3-4) and that the braided combination disclosed in the Burgess application would have “poor knot strength properties.” Ex. 5 at 2-3. The '511 application eventually issued as the '446 patent.

VI. OPINIONS

A. “PE” as described and claimed in the '446 patent does not include UHMWPE

I understand from my discussions with John Witherspoon that the Court will ultimately interpret the meaning of the claim language. In order to assist the Court with interpreting the claim language, I am providing in this section of my report an explanation of why I believe the '446 patent does not include UHMWPE and why a person of ordinary skill in the art would not understand the term “PE,” as it is described and claimed in the '446 patent to include UHMWPE. As I mentioned in my first report, it is my opinion that a person of ordinary skill in the art, in February 1992,

had an undergraduate degree in engineering or science and several years (e.g., approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.

It is my opinion that a person of ordinary skill in the art would not understand that the term "PE," as described and claimed in the '446 patent, includes UHMWPE. The reasons for my opinion include the same reasons I previously mentioned as to why I believe the '446 patent specification does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE.

I add some additional comments. It is my understanding, from the legal expert, that the prosecution history of a patent plays a role during the claim construction process. I have reviewed the prosecution history of the '511 application and it is my opinion that a person of ordinary skill in the art would understand that the applicants argued that UHMWPE was *not* part of their invention.

As I described above, in response to the patent examiner citing the Burgess application in rejecting claims 21-24, Ethicon's attorney argued that it would be bad to use UHMWPE for a suture because it has low elongation and poor knot strength properties. The Ethicon attorney also asserted that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester and/or nylon – the combination disclosed in the Burgess application – the braid would have "poor knot strength properties." (Ex. 5 at 2, 3) and "he would

inevitably design an unacceptable suture.” Ex. 5 at 3-4. It is my opinion that a person of ordinary skill in the art reading these remarks made by Ethicon’s attorney would clearly understand that it was Ethicon’s position that UHMWPE is *not* part of the invention of the ‘446 patent.

Another reason why I believe UHMWPE is not included within the meaning of “PE” as it is described and claimed in the ‘446 patent is because there is no mention at all within the ‘446 patent that “PE” can be used to impart strength to the braid. It was known at the time that UHMWPE was an extremely strong material, and as I explained in my previous report, there were several suggestions to use UHMWPE for suture because of its strength component. The evidence in this case shows that Ethicon and the inventors knew that UHMWPE has great strength. The Ethicon attorney, when responding to the Burgess rejection, specifically states that UHMWPE “has great strength properties.” In addition, Dr. Steckel testified that during the development work that lead to the ‘446 patent he knew that UHMWPE had great strength. Ex. 6 at 190:18-21. If the inventors intended for the described “PE” to include UHMWPE, one would expect that they would have specifically mentioned “PE” as a material that can be used to impart strength to the suture. Yet there is absolutely no mention of “PE” when the patent discusses materials that add strength to the suture. The absence of any such discussion, particularly in light of Ethicon’s knowledge, would strongly suggest to

a person of ordinary skill in the art that the inventors did not mean to convey that UHMWPE fell within the meaning of "PE."

I see that Dr. Brookstein assumed that the meaning of "PE" within the '446 patent includes UHMWPE. Brookstein Report at 9. For the reasons I describe above, it is my opinion that this is an incorrect assumption.

I have also read DePuy Mitek's third supplemental response to Arthrex's Interrogatory No. 2. I understand that DePuy Mitek has asserted that Arthrex's statements regarding the meaning of "PE" within the context of the '446 patent are "wrong" and that "Arthrex's citations are to certain preferred embodiments." I disagree.

It is my opinion that a person of ordinary skill in the art reviewing, for example, the background portion of the '446 patent specification would understand that the discussion is not limited to a preferred embodiment when it describes that "braids of highly lubricious polymers" will be highly pliable but they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25. This general description of highly lubricious polymers is consistent with what was known in the art about general purpose PE and inconsistent with what was known in the art about UHMWPE. It is also my opinion that the specification is generally describing lubricious polymers where it states "a volume fraction of *lubricating yarns* below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about

80 percent may adversely affect the overall strength of the braid.” Ex. 3 at col. 4, ll. 52-54. [Emphasis added.] The entirety of the discussion in the patent specification explains that there is a tradeoff between the two fiber-forming materials – lubricious but weak versus strong. The point made by the inventors is that gains in pliability and handleability by using the combination of lubricious, but weak materials with a stronger material outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. These observations in the specification go far beyond the “preferred embodiment.”

- B. There is a substantial difference between UHMWPE and the first fiber-forming materials of claim 1 of the ‘446 patent

I understand that Dr. Brookstein contends that if UHMWPE is not included within the meaning of “PE” of claim 1 of the ‘446 patent, and there is no literal infringement, then there is infringement under the doctrine of equivalents. I have been informed by the legal expert that in order for infringement to be found under the doctrine of equivalents, the difference between the claim limitation and the alleged “equivalent” portion of the accused product must be insubstantial. For the reasons described below, it is my opinion that the difference between UHMWPE and any of the first fiber-forming materials of claim 1 of the ‘446 patent is substantial.

For example, as I stated in my first report, the ‘446 patent describes that the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The materials described as first fiber-forming materials

are PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The materials described as second fiber-forming materials are PET, nylon and aramid.

The specification also states that the first fiber-forming materials are lubricious materials that act as lubricating yarns to improve the overall pliability and handling characteristics of the braid. The specification explains that these lubricious materials are too weak to be used alone for most suture applications, and therefore, the second fiber-forming materials are added to improve the overall strength of the braid.

The description in the specification of the first fiber-forming materials is very different from UHMWPE. Unlike the first fiber-forming materials, which are described as being lubricious but relatively weak, UHMWPE is a well-known, highly specialized fiber material with strength properties that are far superior to those of any of the first fiber-forming materials of claim 1, including general purpose PE. Thus, it is my opinion that the difference between UHMWPE and the first fiber-forming materials is substantial.

In addition, while the specification describes that the second fiber-forming materials of claim 1 of the '446 patent are added for strength, it is the UHMWPE that is added to Arthrex's FiberWire suture for increasing its strength. Even Dr. Brookstein recognizes that fact. Brookstein Report at ¶ 63. This is the exact opposite of what the '446 patent describes. I find this to be another substantial difference.

Further, when Arthrex and Pearsalls developed the FiberWire suture, Arthrex created an entirely new category of medical products called high-strength suture. Prior to FiberWire, there was no such product on the market. It is the UHMWPE that makes FiberWire so strong. As I previously mentioned, there is no indication at all within the '446 patent that a high-strength suture was even contemplated by the inventors. To the contrary, the inventors had conceded the fact that there was a tradeoff necessary in having a suture that had better handleability and pliability – that tradeoff was lower strength. That is why the specification repeatedly states that the object of the invention is to achieve better handleability and pliability without appreciably sacrificing physical characteristics, including most specifically, strength. Nowhere is there any description or teaching within the '446 patent that the resulting suture will have strength that is far superior to the prior art sutures identified in the patent. In my opinion, this is another substantial difference.

Putting it in terms of the function/way/result test, as did Dr. Brookstein, it is my opinion that the difference between the function performed by the UHMWPE in FiberWire is very different than that of the first fiber-forming materials of claim 1 of the '446 patent. As I stated above, the function performed by UHMWPE in FiberWire is to impart tremendous strength to the FiberWire suture, whereas the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture. For these same reasons,

it is also my opinion that the way in which the UHMWPE performs in Arthrex's FiberWire suture is substantially different from the way in which the first fiber-forming materials perform in the suture of claim 1 of the '446 patent.

It is further my opinion that the result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different. As I stated earlier, when Arthrex and Pearsalls developed FiberWire, Arthrex introduced the first high-strength suture into the marketplace. There is no indication within the '446 patent that such a high-strength suture was contemplated. If it were, one would expect it to be mentioned in the specification, especially since such a suture would be far superior to any suture that was known at the time, at least for the orthopedic applications for which FiberWire is used. Since the use of UHMWPE to impart strength results in a very different suture than that contemplated by using the first fiber-forming materials of the '446 patent, this is another substantial difference.

Dr. Brookstein appears to state that as long as a material used for the first set of yarns contributes a property that is different than a yarn from the second set, that material is equivalent to the "first fiber-forming material" of claim 1 of the '446 patent. Brookstein Report at 20-23. It is my opinion that this can not be true since it would mean that any suture having two different materials braided together in direct intertwining contact would fall within the claims of the '446 patent. As I understand it, the PTO examiner rejected a claim this broad. Ex. 4 at 4.

- C. UHMWPE is used in FiberWire to impart strength and PET is used in FiberWire to improve handleability

As I previously mentioned, the specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.

- D. The basic and novel characteristics described in the '446 patent are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties

I have been asked to provide my opinion regarding what a person of ordinary skill in the art in February 1992 would understand to be the basic and novel characteristics described in the '446 patent. It is my opinion that a person of ordinary skill in the art, in February 1992, reading the specification of the '446 patent would understand the basic and novel characteristics to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

The specification also describes that there is a tradeoff between the two fiber-forming materials that make up the two dissimilar yarns – one being lubricious, but

weak, the other being strong. The tradeoff is that the gains achieved in pliability and handleability by using the combination outweighs the loss of suture strength resulting from combining a weaker lubricious material with the stronger material. According to the specification, the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties.

The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 3 at col. 1, ll. 11-15, l. 24) and "bending rigidity," (Ex. 3 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

One handleability characteristic specifically identified in the patent is "knot tie down." Ex. 3 at col. 6, ll. 7-8. Knot tie-down is a well-known suture handleability characteristic intended to be a measure, which can be either objective or subjective, of the ability of a knot formed in the suture to slide down the suture. Some other factors that can be measured which indirectly relate to knot tie-down include braid chatter (i.e., the smoothness of the braid) and the coefficient of friction (another objective measure of smoothness) of the braid surface.

With regard to knot tie-down, the specification states that while a coating can be added "*to further improve* the handleability and knot tiedown performance of the braid" (Ex. 3 at col. 6, ll. 5-8) [emphasis added], it also states that if the surface of the braid contains "a significant fraction of the lubricious yarn system, the . . . coating may be eliminated." Ex. 3 at col. 6, ll. 13-17. In other words, it is my opinion that the '446

patent is telling a person of ordinary skill in the art that the handleability (*e.g.*, knot tie-down performance) is enhanced due to the braided construction of two dissimilar materials braided together, indeed improved so much in certain configurations that the need for coating can be eliminated.

In addition to pliability and knot tie-down, there are other suture handleability characteristics that were well known in the art at the time of the invention, and therefore, would be understood by a person of ordinary skill in the art to be included in improved handleability, as it is used in the '446 patent. They include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. The specification specifically or implicitly mentions some of these (*e.g.*, knot security, knot stability, compliance, stiffness, coefficient of friction, lack of chatter). The others were well known in the suture art at the time of the invention and they were also recognized as such by Ethicon as well. I have reviewed Ethicon documents specifically mentioning these suture handleability characteristics, including documents during the development that lead to the '446 patent. Ex. 7. Mr. Jamiolkowski, one of the original inventors, also confirmed that suture handling properties includes knot tie-down, tactile feel (or hand), pliability, knot security and chatter. Ex. 8 at 140:5-24; 165:16-166:3. Dr. Steckel, another inventor, also confirmed that suture handling is "the ease of manipulation by the surgeon," with handling properties including "pliability, its roughness, smoothness,

and its frictional properties against itself,” and also including chatter and knot tiedown. Ex. 6 at 77:3-78:2; 79:19-23.

The ‘446 patent describes the “physical properties” of the braid in terms of tensile strength and knot strength. Ex. 3 at col. 2, ll. 66; col. 8, ll. 19-21, Table. Knot security is also mentioned as a property that is not sacrificed with improvements in pliability and handling properties. Ex. 3 at col. 2, ll. 66. Knot security provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking. Ex. 3 at col. 6, ll. 36-39.

I have reviewed Dr. Brookstein’s report and I understand that he has been asked to assume that “the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.” Brookstein Report at 9.

I disagree with that assumption for the reasons stated above. In addition, Dr. Brookstein’s report ignores much of what is taught in the specification. For example, while the specification does disclose direct intertwining contact between two dissimilar yarns, the ‘446 patent specification also discloses that the desired, novel result of this construction is a suture with better handleability and pliability performance without significantly sacrificing its physical properties. This is also consistent with Mr.

Jamiolkowski's statements. Ex. 8 at 163:11-20. Therefore, I believe Dr. Brookstein's assumption regarding the invention is inaccurate.

E. The coating added to Arthrex's FiberWire suture materially affects the pliability, handleability and physical properties of FiberWire

1. Coating materially affects suture handleability

It is my opinion that a person of ordinary skill in the art in February 1992 would understand the '446 patent to be teaching that coating materially affects suture handleability, including knot tiedown. For example, the '446 patent specification itself recognizes coating's effect on these properties where it states that coating the heterogeneous braid will "further improve the handleability and knot tiedown performance of the braid." Ex. 3 at col. 6, ll. 5-8.

Further, it was widely known and undisputed in the suture art in February 1992 that coating materially affects suture handling properties, including knot tie-down, and pliability. For example, there are many patents, including many Ethicon patents, that describe how coating affects these specific handling properties of suture. See, e.g., Ex. 9 at Abstract, col. 1, ll. 14-18; Ex. 10 at col. 1, ll. 11-15; Ex. 11 at col. 1, ll. 8-12; Ex. 12 at col. 1, ll. 12-15. There are also many articles on the subject as well. See, e.g., Ex. 13 at 525. I have also reviewed Ethicon documents stating the same thing. For example, in connection with the development of Ethicon's Panacryl suture, Ethicon stated that "the purpose of coating the Panacryl braided suture is to provide the suture with good

handling properties . . . such as knot slide, suture roughness, and knot security.” Ex. 14 at 1.

This is also consistent with DePuy Mitek documents I have reviewed, all of which confirm that coating affects suture handling properties. Ex. 15 at 2. I have also reviewed Arthrex documents that also state that coating on the FiberWire product affects specific handling properties. For example, the directions for use (DFU) for FiberWire states that the coating acts as a lubricant for suture sliding, knot tying and ease of passing suture through tissue. Ex. 16. Dr. Steckel, one of the inventors of the ‘446 patent, also stated during his deposition that the reason why people coat sutures is to improve handleability and knot tie-down. Ex. 6 at 296:3-7.

It is also generally known in the suture art that coating materially affects a suture’s tactile feel or smoothness. Ex 10 at col. 1, ll. 11-12. This is a subjective test usually performed by a surgeon in which the surgeon runs the suture through his hands and qualitatively evaluates its “feel.” Sometimes, the surgeon attaches a quantitative value to the tactile feel of the suture so that it can be compared relative to other coated or uncoated sutures. I have reviewed Ethicon documents in which a tactile feel test is performed in evaluating different coating type and concentrations. Ex. 17 at Table 24.

Further, it is generally understood in the suture art that coating materially affects how easily a suture passes through tissue – commonly known as “tissue drag.” The

effects of coating on tissue drag are described in Ethicon patents (Ex. 10 at col. 1, ll. 11-15) as well as other Ethicon documents. Ex. 18 at 11.

It was also generally understood in the suture art in February 1992 that coating materially affects suture pliability/bendability. It was known that adding coating to a suture could either improve pliability/bendability or adversely affect pliability/bendability. See Ex. 9 at col. 1, ll. 14-18; see also Ex 3 at col. 1, 20-22; col. 6, ll. 15-17.

I have also reviewed tests that show that the coating on FiberWire materially affects various handleability or pliability characteristics. In addition, I have reviewed results of a test entitled "Knot Tiedown" dated February 16, 2004 (Ex. 19). I understand the test was conducted by Arthrex and was intended to objectively show how coating affects knot tiedown.

The objective of the test was to simulate a surgeon's half-hitch knot and to determine the amount of force required to initiate movement of the knot down the line of suture – much like a surgeon moves the knot down the line of suture toward the wound. The test was conducted on both coated and uncoated samples of Arthrex's US No. 2 FiberWire suture. The test results for the two sutures were very different. By this test, Arthrex demonstrated that when coating is added to FiberWire suture, it becomes

approximately 2-1/2 times easier to slide the knot down the suture.¹ In my opinion, these results demonstrate that coating materially affects knot tiedown of FiberWire suture.

In addition to the above described test, I have suggested tests of my own on coated and uncoated samples of FiberWire suture. Like the Arthrex test, the tests I suggested were objective in nature and also demonstrate that coating materially affects the handleability or pliability characteristics of FiberWire suture. The tests were conducted by the Center for Tribology in Campbell, California ("CETR"). The results are attached as Ex. 20. I understand that many of the world's leading suture manufacturing companies – including Ethicon and U.S. Surgical Corp. – use CETR to conduct various tests on their own suture.

Specifically, the tests conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each materially affected by the addition of coating. For example, the knot tie-down (knot run-down) test measures the force required to initiate movement of a half-hitch knot formed on the suture and also the force required to slide the knot down the suture. The results of the knot tie-down test are a function of the smoothness of the surface of the braid. The results of the knot tie-down test performed by CETR

¹ The mean peak force required to initiate slippage of the knot on the uncoated suture was 32.0N, whereas only 12.7N were required to initiate slippage of the knot on the coated suture.

It is generally known in the suture art that coating materially affects a suture's knot security. See Ex. 22 at 211, 216; see also Ex. 13 at 528. Knot security is the measure of how many "throws" of a surgeon's knot are required to hold a knot secure.

Generally speaking, the fewer the better. During a knot security test, a series of knots are thrown (i.e., formed and then slid down the suture to the desired location where they are tightened), then a pull test is conducted in which force is applied to the series of knots. If the suture breaks before the knot slips (i.e., loosens), then the suture has passed the test. If the knot slips before breaking, the suture fails.

I have reviewed patents that describe coating having both an adverse effect and a positive effect on suture knot security. See, e.g., Ex. 23, Ex. 24. The results appear to be dependent on the specific coating applied to the suture. In any event, the patents describe to a person of ordinary skill in the art that coating does materially affect knot security.

Furthermore, one of the tests that I suggested be performed by CETR conclusively demonstrates that coating does materially affect knot security of FiberWire. Specifically, much less force was required to undo the knot tied on the coated FiberWire as compared with the uncoated FiberWire, thus conclusively showing that the coating added to FiberWire materially affects its knot security. Ex. 20 at 5-7.

I have also reviewed knot strength test data captured by Pearsalls over a 4-1/2 year period which show that the addition of coating increases the knot strength of

FiberWire. Ex. 25. The data lists knot strength measurements of the heterogeneous braids used in Arthrex's FiberWire suture. The measurements were taken prior to and after coating. This is consistent with Ethicon documents I have reviewed which also describe an increase in knot strength after a coating has been applied to the suture. Ex. 14. Based on the test data I have reviewed, supported by Ethicon's documentation, it is my opinion that the coating applied to FiberWire materially affects knot strength of the suture.

3. Dr. Brookstein's Report

As explained above, I disagree with Dr. Brookstein's assumption that "the basic and novel characteristics [of the invention] are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Brookstein Report at 9. I also disagree with his conclusion that coating does not affect those basic and novel characteristics. While Dr. Brookstein states some conclusions (paragraph 36), he offers no technical evidence to support his conclusions.

Dr. Brookstein refers to Scanning Electron Micrographs and concluded that "the coating on the FiberWire suture does not substantially permeate the braided structure and does not reside between the braid yarns" and "that the coating only appears on the surface of the braid." Brookstein Report at ¶ 39.

Based on my review of the three micrographs, it appears that they are very different and that they are too unclear to draw any conclusions from them. Despite the lack of clarity, however, it appears that the individual braid filaments are grouped together to a much greater degree in the Tab G micrograph than they are in the Tab E micrograph. This is an indication that coating has permeated into the braid.

In any event, Dr. Brookstein's conclusions are inconsistent with the findings discussed below. In addition to the tests described above, CETR also conducted a scanning electron microscopy (SEM) examination of coated and uncoated FiberWire suture. My review of the scans performed to date appears to indicate that the coating does extend into the braid. Ex. 20 at Fig. 14. This is consistent with the effect coating has on FiberWire's pliability, as described above.

F. The nylon added to TigerWire suture materially affects its pliability

I understand that Arthrex's TigerWire suture has the same construction as FiberWire suture except that one of the PET carriers is replaced with nylon 6,6. All the reasons discussed in connection with FiberWire also apply to TigerWire. Further, it is well known in the art of manufacturing and/or processing of fibers that nylon 6,6 fibers of the type used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Ex. 26. Therefore, the act of removing one PET carrier and replacing it with a nylon 6,6 carrier during the braiding process, as is done with TigerWire, introduces a less pliable material into the composite braid.

It is also my understanding from discussions with Bill Benavitz of Arthrex that the diameter of the nylon 6,6 fibers used in TigerWire is greater than that of the PET which it replaces. Therefore, the nylon 6,6 fiber makes up a greater percentage of the braid cross-section area than does the PET fiber it replaces. Mr. Benavitz also informed me that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. In addition, I held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. I also conducted the drape test on the two samples and found that the FiberWire conformed to the shape of my finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. For these reasons, it is my opinion that the addition of nylon 6,6 in TigerWire materially affects its pliability. Moreover, the course feel would suggest that the addition of the nylon would adversely affect knot tie-down.

Dr. Brookstein stated that the purpose of the nylon included in TigerWire is for visual identification, and refers to Peter Dreyfuss's testimony to support his opinion. Brookstein Report at ¶ 46. Whether or not Dr. Brookstein's report is accurate, it does not change the fact that, as explained above, the addition of nylon materially affects TigerWire's pliability.

- G. Adding an adhesive to FiberStick suture materially affects its handleability

I understand that an adhesive material is applied to one end of Arthrex's FiberStick suture to stiffen a 12-inch length of the end of the suture. All the reasons discussed above in connection with FiberWire apply to FiberStick. In addition, based upon my review of Arthrex's marketing materials (Ex. 27), I understand that the stiffened portion materially improves the handleability of the suture in its intended application by easing passage of the suture through cannulated instruments and/or spinal needles. I also understand that the use of FiberStick also alleviates the need for monofilament or wire suture shuttles. Further, the stiffening of FiberStick restricts mobility between the fibers that make up the braid and also significantly restricts pliability/bendability of the suture. Therefore, it is my opinion that the addition of the adhesive to FiberStick materially affects the handleability of the suture.

H. The braids manufactured by Pearsalls are suitable for use in applications other than FiberWire sterilized surgical suture

The braids manufactured by Pearsalls for use in FiberWire are composed of UHMWPE and PET yarns braided together around a core of UHMWPE. The braids manufactured by Pearsalls are not sterilized, nor are they tipped. It is well known in the art of manufacturing and/or processing of fibers that the same construct of UHMWPE braided together with PET and surrounding a core of UHMWPE is also suitable for use as fishing line. For example, the Burgess application (Ex. 28) discloses a fishing line made of UHMWPE and polyester. Burgess also discloses that the braids may be coated – a process that is also performed by Pearsalls on the braids used for

EXHIBIT 7

PEARSALL SUTURES

PRODUCTION SPECIFICATION

KRYSTON SILKWORM (91) - 81b knot strength

Computer Code 81SW8LB-020/040

Process Route:

- 1) Producer package raw yarns
- 2) Wind to carrier bobbin
- 3) Braid - 8 carrier machine
- 4) Wind to dye cone
- 5) Dye
- 6) Wind to final package
- 7) Label and pack

Process Route Detail:

- 2) 2 Carriers - 150 denier Dyneema HPPE Polyethylene (333 d'tex - 77.3%) 2 Carriers - 49 d'tex Trevira Polyester Type 712. (98 d'tex - 22.7%)
- 3) Braid - 12 PPI (Haul off 1½") Machine state runnage 22,500 m/kg.

Carrier loading *
 0*0

- 4) Wind to plastic dye cone, approximately 500g (Yellow colour tie)
- 5) Dye colour recipe 7727 - 81b
- 6) Final package - small black plastic reel - 20/40m
- 7) Label as below, pack in clear plastic case, place in polythene bag with knotting instructions, staple header card and pack in polythene bags of 10.



SJW 14.1.91
Ref: DT 212/49/19

PEARSALLS SUTURES

PRODUCTION SPECIFICATION

KRYSTON SILKWORM (91) 10 lb knot strength

Computer Code 81SW10LB-020/040

Process Route:

- 1) Producer package raw yarns
- 2) Wind to carrier bobbin
- 3) Braid - 8 carrier machine
- 4) Wind to final package
- 5) Label and pack

Process Route Detail:

- 2) 2 Carriers - 150 denier Dyneema HPPE Polyethylene
(333 d'tex - 50%)
2 Carriers - 157 d'tex spun dyed medium tenacity Polyester
(334 d'tex - 50%)

(1 Carrier Palissandro Brown, 1 Carrier Malva Green)
- 3) Braid - PPI 12 (Haul off 1½") machine state runnage 15,000 m/kg
Carrier Loading $\begin{matrix} * & o \\ o & * \\ * & o \end{matrix}$ (Red colour tie)
- 4) Final Package: Small black plastic reel 20/40m
- 5) Label as below, pack in clear plastic case, place in polythene bag with knotting instructions staple header card and pack in polythene bags of 10.

SJW 14.1.91
Ref: DT 212/49/23

PEARSALLS SUTURES

PRODUCTION SPECIFICATION

KRYSTON SILKWORM (91) - 151b knot strength

Computer Code 81SW15LB-020/040

Process Route:

- 1) Producer package raw yarns
- 2) Wind to carrier bobbin
- 3) Braid - 12 carrier machine
- 4) Wind to final package
- 5) Label and pack

Process Route Detail:

- 2) 3 Carriers - 150 denier Dyneema HPPE Polyethylene (500 d'tex - 49.9%)
3 Carriers - 167 d'tex spun dyed medium tenacity Polyester
(501 d'tex - 50.1%)

Colour Ref: 1 Carrier - Malva Green, 1 Carrier - Palisandro,
1 Carrier - Teak.

- 3) Braid - PPI 12 (Haul off 50mm) machine state runnage 9,700 m/kg.
Carrier loading x (Pink colour tie).

o
o
x x

- 4) Final Package: Small black plastic reel 20/40m.
- 5) Label as below, pack in plastic case, place in polythene bag with knotting instructions. Staple header card and pack in polythene bags of 10.



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Prosecution Counsel Only"

PR 08402

January 1991

PEARSALLS SUTURES

PRODUCTION SPECIFICATION


KRYSTON SILKWORM (91) 251b Knot Strength

Computer Code 81SW25LB-020/040

Process Route:

- 1) Producer package raw yarns
- 2) Wind to carrier bobbin
- 3) Braid - 16 carrier machine
- 4) Wind to final package
- 5) Label and pack

Process Route Detail:

- 2) 4 Carriers - 150 denier Dyneema HPPE Polyethylene
(667 d'tex - 76.9%)
4 Carriers - 50 d'tex Viscosuisse spun dyed black polyester
(200 d'tex - 23.1%)
- 3) Braid - PPI 16 (Haul off 2 $\frac{1}{8}$ ") machine state runnage 8400 m/kg
Carrier loading  (Green colour tie)
- 4) Final package - small black plastic reel 20/40M
- 5) Label as below, pack in plastic case, place in poly bag with knotting instructions. Staple header card. Pack in poly bags of 10.

Ref: DT212/45/1 (55015)
SJW 22.01.91



EXHIBIT 8

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

_____)	
DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	LEAVE TO FILE GRANTED:
)	AUGUST 28, 2006
a Delaware Corporation)	
)	
Defendant.)	
_____)	

SUBSTITUTE DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S
CONCISE STATEMENT OF MATERIAL FACTS IN SUPPORT OF THEIR MOTION
FOR SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules, District of Massachusetts, Defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") hereby submit their concise Statement of Material Facts in Support of their Motion for Summary Judgment against plaintiff DePuy Mitek, Inc. ("DePuy Mitek"):

1. Plaintiff Depuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17.¹
2. Defendant Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. FiberWire suture and its related products TigerWire and FiberStick ("collectively "FiberWire") are among those products and are the ones accused of infringement of U.S. Patent No. 5,314,446 ("the '446 patent"). Ex. 16.

¹ Except where otherwise indicated, "Ex." refers to Exhibits to the Memorandum in Support of Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Motion for Summary Judgment.

3. Defendant Pearsalls, a United Kingdom company, is a braid manufacturer which makes the braids that eventually become FiberWire suture.

4. Ethicon, a Johnson & Johnson company, is related to DePuy Mitek and the original owner of the '446 patent. Ex. 18.

5. In 2001, Arthrex introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5.

6. FiberWire was so new and revolutionary that it spawned a new category of suture called "high-strength" suture. Ex. 2 at 2; Ex. 4 at 146:7-14.

7. FiberWire suture was the first "high-strength" suture introduced into the market. Ex. 2 at 2; Ex. 4 at 146:7-14.

8. FiberWire was more than twice as strong as the sutures conventionally used in orthopedic surgery, including Ethibond, the leading suture for the orthopedic market sold by Ethicon. Ex. 2 at 8.

9. FiberWire obtains its strength because it contains ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials ever created.. Ex. 3 at § 1.

10. After seeing the impact of FiberWire, DePuy Mitek realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5.

11. DePuy Mitek's original idea was to introduce a "me too" suture that mimicked FiberWire. Ex. 5. In late 2004, DePuy Mitek introduced its own high strength suture called Orthocord, which also includes UHMWPE. Ex. 6.

12. Shortly before filing this lawsuit, the '446 patent was assigned from Ethicon to DePuy Mitek. Ex. 7. In this lawsuit, DePuy Mitek alleges that defendants infringe claims 1, 2, 8, 9 and 12 of the '446 patent ("the asserted claims").

13. Neither Ethicon, nor DePuy Mitek has never made a commercial product covered by the '446 patent. The '446 patent is a paper patent. Ex. 9.

14. Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at 103:23-104:17.

15. At the time, a standard braided suture was Ethibond, a suture made entirely of PET polyester, which was braided to form the suture. Ex. 4 at 135:4-7.

16. Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

17. Ethicon built and test heterogeneous braids, made of PTFE and PET, by February 2, 1989. None of these braids, however, were sterilized. Ex. 19 at 225:5-8.

18. Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent. Ex. 10 at 345:7-10.

19. During his development work, Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down even without a coating." Ex. 21 at DMI 2666.

20. Dr. Steckel knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex.5 (to *Markman* Brief) at 190:12-191:3.

21. Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braids. Ex. 8 at cover page.

22. The specification of the '446 patent begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 8 at col. 1, ll. 5-25.

23. The specification cautioned that mechanisms, such as coating, will adversely affect braid mobility and explained that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 8 at col. 1, ll. 26-29.

24. The first example presented in the specification is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 8 at col. 1, ll. 29-31.

25. The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 8 at col. 2, ll. 22-28.

26. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 8 at col. 4, ll. 50-54.

27. The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 8 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 8 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 8 at col. 2, ll. 62-66; col. 6, ll. 7-8.

28. The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 8 at col. 1, ll. 11-15, 24) and "bending rigidity," (Ex. 8 at col. 6, ll. 44-45, col. 8 at Table, ll. 44-46), which are the inverse of pliability.

29. A handling property specifically identified in the '446 patent is "knot tie down." Ex. 8 at col. 6, ll. 7-8.

30. The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Ex. 8 at col. 8, ll. 22, 35 and 38.

31. The specification also discusses the use of coating on sutures. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid." The specification also states that it is better if coating is not used, explaining that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 8 at col. 6, ll. 5-17.

32. Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 8 at col. 4, ll. 11-27.

33. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 8 at col. 4, ll. 35-40. The term PE is never associated with the "strength" yarns.

34. Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Ex. 8 at claim 1.

35. The remainder of the asserted claims ultimately depend from claim 1. Ex. 8 at claims 2, 8, 9, 12.

36. Claim 1 defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid. Ex. 8 at claim 1.

37. As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from heterogeneous braids. Ex. 22.

38. Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ethicon elected to pursue the surgical suture claims. Ex. 23.

39. As originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 22.

40. In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8 to *Markman* Brief).

41. The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ex. 8 (to *Markman* Brief). The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 23 at 4.

42. In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have poor knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line minimal stretchability." [Emphasis in original.] Ex. 24 at 2.

43. Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. Ethicon also told the Patent Office that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 24 at 3-4.

44. Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 25 at 1. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials. Ex. 25.

45. The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 25.

46. The preamble of the claims was also amended to change the term “comprising” to “consisting essentially of.” Ex. 25 at 1.

47. UHMWPE is a stiff material. It is not a pliable material. Ex. 11 at ¶ 56; Ex. 10 at 306:20-307:4.

48. General purpose PE has been used in sutures and other materials for decades and is established as a general purpose commodity polymer. Ex. 3 at § 1.

49. UHMWPE was introduced as in fiber form in 1985 and is considered a specialized high performance product. Ex. 3 at § 1.

50. General purpose polyethylene and UHMWPE are not substitutes for each other. Ex. 12 (to *Markman* Brief) at 22.

51. The key structural characteristics of UHMWPE and general purpose polyethylene, molecular weight and molecular structure very different. Ex. 3 at § 2.

52. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. Ex. 3 at § 2.

53. UHMWPE exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose polyethylene. Ex. 3 at § 2.

54. DePuy Mitek’s expert, Dr. Hermes’ first impression when reading the ‘446 patent was that it “seem[ed] to teach away from UHMWPE.” Ex. 14 (to *Markman* Brief); Ex. 10 at 336:23-23.

55. Based on the teachings of the ‘446 patent, Ethicon’s statements in the prosecution history and the differences between general purpose polyethylene and UHMWPE, the term “PE” in the asserted claims of the ‘446 patent means general purpose polyethylene and does not include UHMWPE. Accordingly, FiberWire does not contain a material from the first set of

yarns and does not infringe the asserted claims of the '446 patent literally or by the doctrine of equivalents.

56. The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. Ex. 8 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8; Ex. 8 at 110:14-20; Ex. 8 at 103:23—104:17.

57. Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. Ex. 34, col. 1, ll. 14-18; Ex. 35, col. 1, ll. 11-15; Ex. 36, col. 1, ll. 12-15; Ex. 37, col. 1, ll. 19-25; Ex. 29 at 11; Ex. 28 at 525; Ex. 39; Ex. 40; Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23; Ex. 14; Ex. 8 at col. 1, ll. 29-31; col. 6, ll. 5-8. As stated above, the '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down.

58. FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Ex. 14.

59. For the reasons stated above, coating affect the basic and novel characteristics of the asserted claims of the '446 patent and its inclusion in FiberWire precludes infringement of those claims.

NOTE; THE REMAINING FACTS ARE SUBMITTED ONLY IF THE COURT CONSTRUES “PE” TO INCLUDE UHMWPE.

60. United States Patent No. 5,318,575 (“the ‘575 patent”) is prior art to the ‘446 patent. Ex. 15 at cover page; Ex. 8 at cover page.

61. Ethicon did not reduce to practice any product that included all the limitations of the asserted claims of the ‘446 patent before the filing date of the ‘446 because it never built a braid that was sterilized before the filing date, as shown above. “Sterilized” is a limitation of each asserted claim of the ‘446 patent. Ex. 8 at claim 1, 2, 8, 9, 12.

62. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent. The ‘575 patent discloses a surgical suture. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59; Ex. 10 at 212:25-213:5.

63. The ‘575 patent discloses a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Ex. 15 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12; Ex. 15 at claim 1.

64. FIG. 6 of the ‘575 patent discloses a spiroid braid with several yarns (items 26) that are braided in “direct intertwining contact.” Ex. 10 at 201:24-202:5.

65. The ‘575 patent discloses that one of the yarns braided together to form a suture is UHMWPE. Ex. 15 at col. 2, l. 31; Ex. 10 at 197:12-25

66. The ‘575 patent discloses that one of the yarns braided together to form a suture is PET or nylon. Ex. 15 at claim 11; claim 12; Ex. 10 at 198:7-11, 14-18.

67. The ‘575 patent discloses that the suture is attached to a needle. Ex. 15 at col. 5, ll. 41-42.

68. The '575 patent discloses that UHMWPE can be constitute a volume fraction in the braided sheath and core from about 20-80%. Ex. 15 at col. 4, ll. 8-24; Fig.6.

69. For these reasons, the '575 patent renders the asserted claims of the '446 patent invalid for anticipation.

Dated: August 11, 2006

Respectfully submitted,

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Arthrex, Inc. and Pearsalls Ltd.

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	"Way" of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

COPY

DEPOSITION OF: DONALD GRAFTON
DATE: March 14, 2006
TIME: 8:38 a.m. to 1:23 p.m.
LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112
TAKEN BY: Plaintiff
REPORTER: Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER: Gene Howell, CLVS

1 That is knot tiedown. And there's a knot placed in the
2 suture, so -- so tying a knot and knot tiedown are the
3 same things as far as I'm concerned.

4 Q. Okay. You just said tying a knot and knot
5 tiedown is the same thing. My question was slightly
6 different. Knot strength versus -- What is your
7 understanding of knot strength?

8 A. It's the mechanical tensile of the suture's
9 ability to -- to, after tying a knot, before breakage.

10 Q. Did you generally consider knot strength to be
11 determined by tying a knot in a suture and testing it on a
12 tensile --

13 A. Yes.

14 Q. -- testing machine?

15 A. Yes.

16 Q. How about knot tiedown? Is that --

17 A. We didn't test for knot tiedown.

18 Q. So you -- Before, you said knot strength and knot
19 tiedown were the same thing.

20 A. That's why I said that we tested for knot
21 strength -- okay -- for -- of tying a knot. And I
22 consider those the same things. So we didn't -- we didn't
23 test specifically for tying soft tissue down. We tested
24 the knot as tying a knot versus -- what the standard calls
25 for and doing a pull test on it.

1 Deberdino who was a surgeon at Fort Sam Houston, San
2 Antonio. His -- his comments were that he had tied three
3 knots the previous afternoon using the FASTak product of
4 Arthrex -- that's a glenoid labrum device -- and had broke
5 the knots on all three of them. And -- you know -- he
6 said it kind of jokingly. He said, "And I didn't even
7 work out the day before."

8 And so he was trying to be nice about it, but
9 bottom line was your suture sucks. Okay?

10 And so -- you know -- we're in a position where
11 we need to find a suture that will be competitive. I had
12 been to Pearsalls many times working on bioabsorbable
13 products. This was the time that you referred to earlier
14 where I said three to five, and was familiar with suture
15 manufacturing, the steps required to manufacture a suture.

16 One of the trips there, Mr. Lyon had pointed out
17 to me a -- the other products they manufactured, which was
18 fishing line and silk used in decorated drapes. The
19 fishing line used a ultra-high molecular weight
20 polyethylene material that was very strong, and I -- at
21 some point, it was decided that we would try some of that
22 for a suture.

23 I had Pearsalls, mainly through Brian, as being
24 the manufacturing person --

25 Q. Brian Hallett?

1 A. That's correct -- make some Size 2 braided
2 material, send to me, and at the -- coincidentally, at the
3 same time, I had a Dr. Steve Burkhart from San Antonio and
4 a Dr. Casey Chan, who is a R & D guy in knot testing and
5 suture. They were -- they were at Arthrex at the time
6 when this material showed up.

7 We tested the material. The strength was
8 excellent. The knot slippage was very poor, would not
9 hold a knot.

10 So at that point in time, it looked like we would
11 not be able to use an alternative material of ultra-high
12 molecular weight polyethylene because the slippage of the
13 material -- because of the slippage of the material tested
14 with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at
15 that point in time, the -- the product was -- was on hold.

16 I was on a trip to Chicago to the national sales
17 meeting, and I had this idea of adding PET to the
18 ultra-high molecular weight polyethylene to enhance the or
19 reduce the knot slippage of the product. I sent an e-mail
20 to Dr. Steve Burkhart and suggesting that since he was
21 familiar with the testing we had done very recently with
22 just the ultra-high molecular weight PE, of adding the
23 PET, and his -- I'll never forget the e-mail. He thought
24 that was a killer idea.

25 And so I had asked then at that time for Brian

1 Q. Okay. And it didn't have nylon or any other
2 material braided with it?

3 A. No.

4 Q. So the initial prototype was a ultra-high
5 molecular weight polyethylene braided suture prototype, if
6 you will?

7 A. Yes. Size 2.

8 Q. Size 2. And was the initial prototype, was it
9 coated?

10 A. I don't remember.

11 Q. Okay. Do you know if the initial prototype went
12 through any other manufacturing process like stretching or
13 heating, twisting?

14 A. I don't recall.

15 Q. Was the initial prototype 100 percent ultra-high
16 molecular weight polyethylene?

17 A. For the fourth time, yes.

18 Q. Okay. And you tested the initial prototype that
19 was 100 percent ultra-high molecular weight polyethylene
20 with Dr. Burkhardt and Dr. Chen?

21 A. Dr. Casey Chen, correct.

22 Q. Okay. And the test that you conducted with Dr.
23 Burkhardt and Dr. Chen on the ultra-high molecular weight
24 polyethylene was a knot strength test?

25 A. Knot security.

1 Q. Knot security test?

2 A. Yes.

3 Q. Was that the test we drew in Exhibit Number 421?

4 A. That's correct.

5 Q. Okay. And you said the strength was excellent, I
6 believe, of the initial prototype, but the knot slippage
7 was poor; is that right?

8 A. Yes.

9 Q. Okay. When you say the slippage was poor of the
10 initial prototype, what do you mean?

11 A. Less than the tensile strength capability of the
12 existing Arthrex product.

13 Q. So the knot slippage was less than the Tevdek
14 suture?

15 A. Yes.

16 Q. And it was -- knot slippage was such that it was
17 determined that the 100 percent ultra-high molecular
18 weight polyethylene suture prototype wasn't suitable to be
19 developed?

20 A. That's correct. Yes.

21 Q. Okay. Ultra-high molecular weight polyethylene,
22 you said the knot slippage was poor?

23 A. (Witness nods head affirmatively).

24 Q. Ultra-high molecular weight polyethylene, is that
25 a lubricious material?

1 A. Yes.

2 Q. And was the knot slippage of this ultra-high
3 molecular weight polyethylene poor security because of the
4 lubricity of polyethylene?

5 A. Yes.

6 Q. Yes?

7 A. Yes.

8 Q. So then you came up with the idea to braid PET
9 with the ultra-high molecular weight polyethylene to
10 reduce the knot slippage?

11 A. Yes.

12 Q. And when you say knot slippage, we're referring
13 to this knot security test?

14 A. Yes.

15 Q. So are we using the terms knot slippage and knot
16 security interchangeably here?

17 A. You are, yes.

18 Q. In your testimony?

19 A. Yes.

20 Q. So the knot security of the 100 percent
21 ultra-high molecular weight polyethylene was poor, the
22 prototype; right?

23 A. Yes.

24 Q. And your idea was to add the PET and to improve
25 the knot security?

EXHIBIT 11



US005314446A

United States Patent [19]**Hunter et al.**[11] **Patent Number:** **5,314,446**[45] **Date of Patent:** **May 24, 1994**[54] **STERILIZED HETEROGENEOUS BRAIDS**[75] **Inventors:** Alastair W. Hunter, Bridgewater;
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio[73] **Assignee:** Ethicon, Inc., Somerville, N.J.[21] **Appl. No.:** **838,511**[22] **Filed:** **Feb. 19, 1992**[51] **Int. Cl.⁵** **D04C 1/00**[52] **U.S. Cl.** **606/231; 606/228;**
87/7; 87/9; 428/370[58] **Field of Search** 606/228, 230, 231;
87/7, 8, 9; 428/225[56] **References Cited****U.S. PATENT DOCUMENTS**

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes*Assistant Examiner*—Chris Raimund*Attorney, Agent, or Firm*—Hal Brent Woodrow[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

U.S. Patent

May 24, 1994

Sheet 1 of 3

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FIG-1

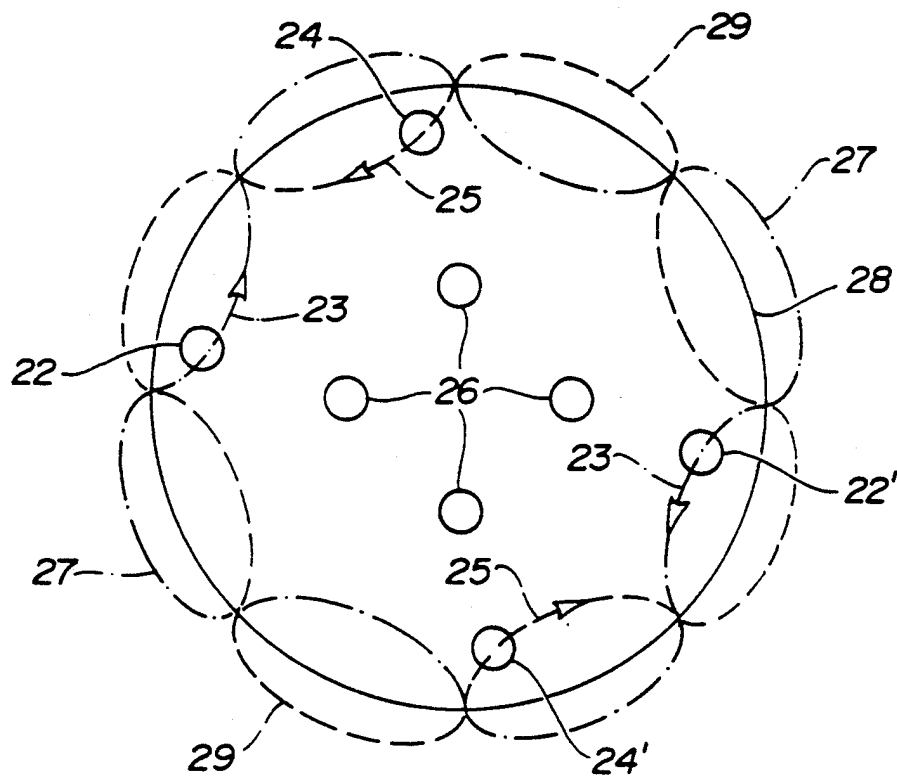


FIG-2

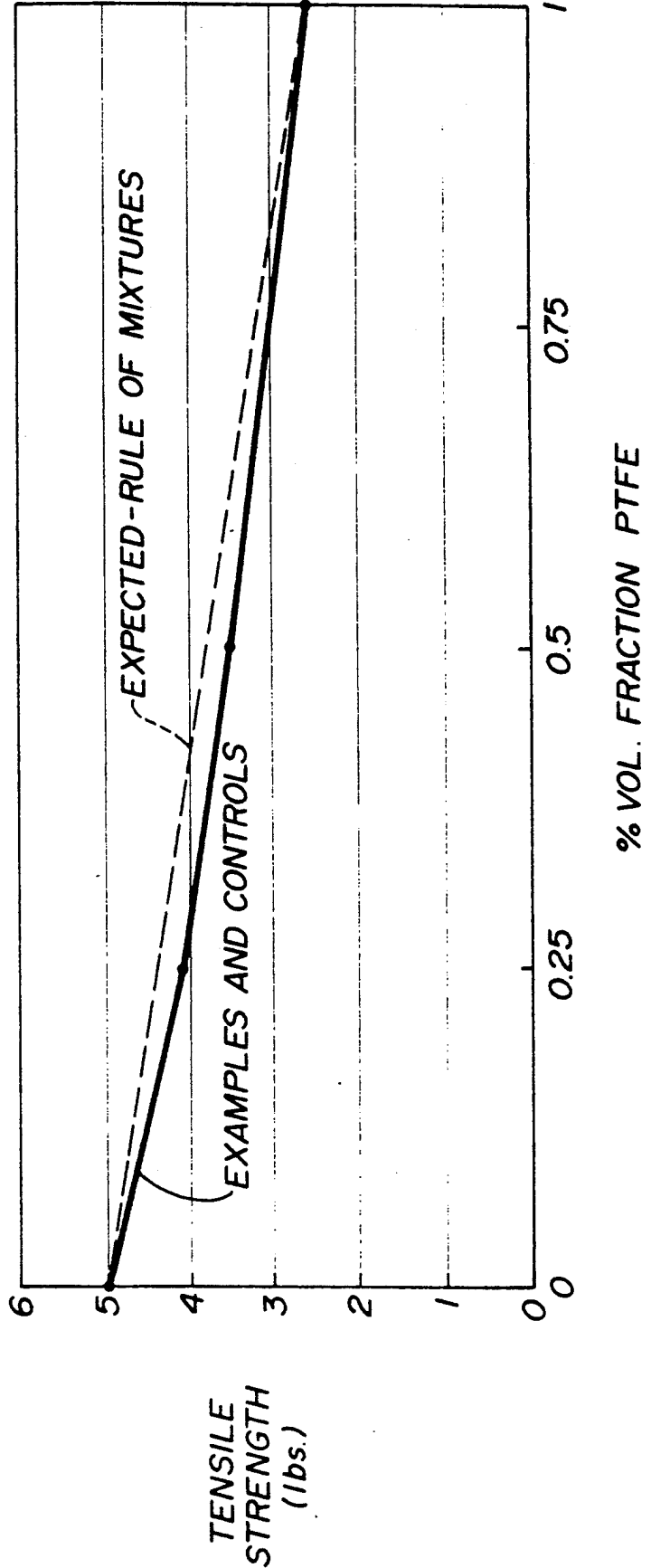
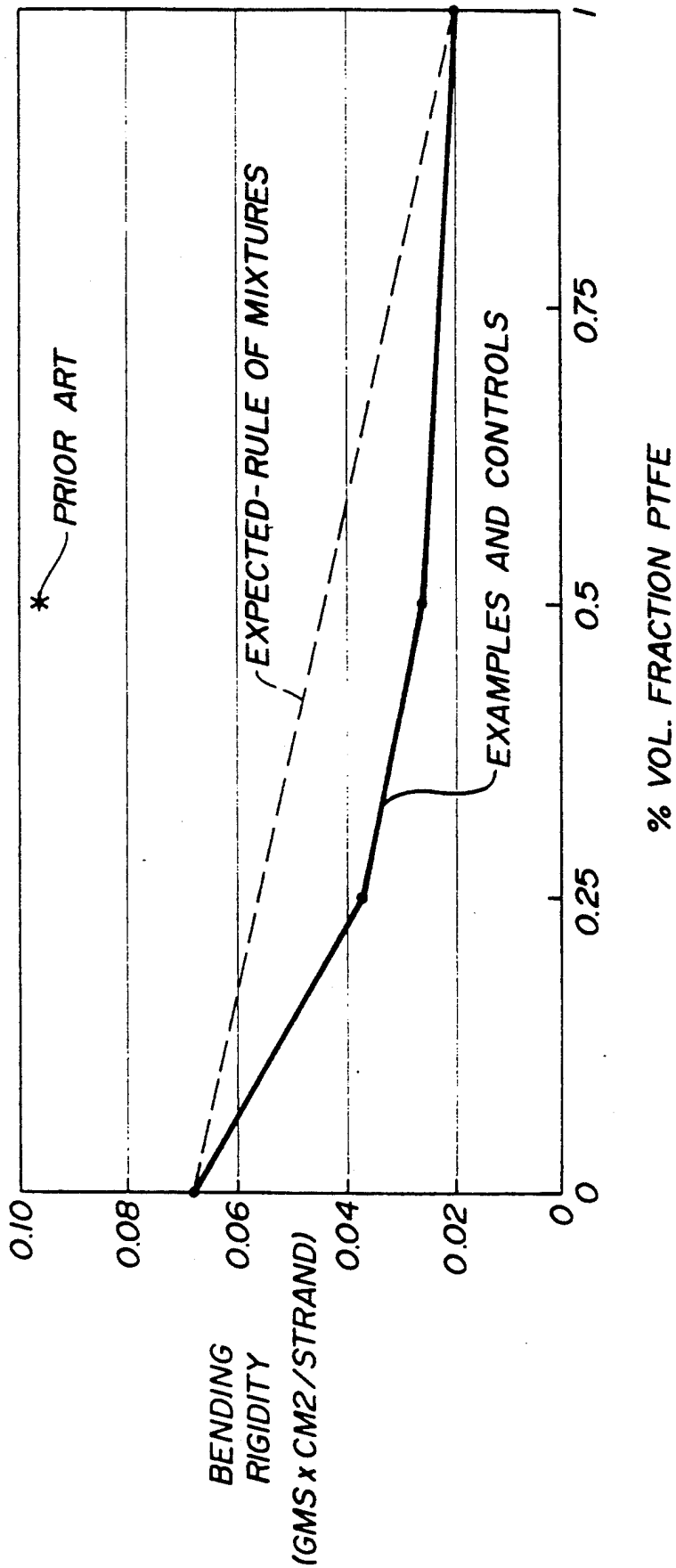


FIG-3



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2

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

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the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

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ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Dekker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

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24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

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braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

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CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f a) (P_a) + (V_f b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and $V_f a$ and $V_f b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

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- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
 - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
 - c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

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6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
8. The surgical suture of claim 1 wherein the second set of yarns is PET.
9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
12. The surgical suture of claim 8 wherein the suture is attached to a needle.
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EXHIBIT 12

Confidential Deposition of:
Ilya Koyfman

February 22, 2006

Page 1

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2

UNITED STATES DISTRICT COURT

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DISTRICT OF MASSACHUSETTS

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C.A. No. 04-12457 PBS

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DePUY MITEK, INC.,

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A Massachusetts Corporation,

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Plaintiff,

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v.

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ARTHREX INC.,

11

A Delaware Corporation,

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Defendants.

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* * *CONFIDENTIAL* * *

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DEPOSITION OF ILYA KOYFMAN

17

Somerset, New Jersey

18

February 22, 2006

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Reported by:

21

MARY F. BOWMAN, RPR, CRR

22

JOB NO.: SE232

23

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1 KOYFMAN - Confidential

2 A. Yes.

3 Q. Did you prepare this document?

4 A. Yes.

5 Q. What is it?

6 A. It's a product development strategy
7 for Orthocord.

8 Q. Can you turn to page DMI 082160.

9 A. OK.

10 Q. I want to ask you a little bit about
11 the -- what comes under the heading "braiding
12 through coating," et cetera. Particularly the
13 last paragraph on the page. The sentence that
14 says, "Coating selection depends on maintaining a
15 fine balance between suture tie-down and knot
16 security."

17 A. Um-hm.

18 Q. What did you mean by that sentence?

19 A. The prime reason for applying coating
20 is to have a good tie-down, good tie-down and
21 tissue passage and so forth. When you apply
22 coating, you might affect other properties. So
23 that's what I meant, you have to have a balance.

24 Q. The other properties being knot
25 security?

1 KOYFMAN - Confidential

2 A. Yes.

3 Q. How can coating affect knot security?

4 A. If you apply too much of a slippery
5 coating, it would reduce the friction in the knot
6 and it would reduce knot security. You have to
7 put more throws to keep the knot together.

8 Q. Could you explain what you mean when
9 you say more throws to keep a knot together and
10 what relationship that has to knot security?

11 A. When you approximate tissue, you apply
12 a surgical throw. Each of this is a throw
13 (indicating). Two of them make a knot. So
14 sometimes you have to apply three knots to keep
15 the knot secure.

16 Q. So it is the number of knots that you
17 need to keep the knot secure?

18 A. Yes, yes, and the force applied to
19 take it apart.

20 Q. The next sentence in this paragraph
21 says, "Coatings provide the lubricity necessary to
22 achieve smooth tie-down in knot slide
23 performance." Do you see that?

24 A. Yes.

25 Q. What did you mean by that sentence?

1 KOYFMAN - Confidential

2 MR. BONELLA: Object to form.

3 Q. Let me turn to table 4, which says
4 knot security. Correct?

5 A. Yes.

6 Q. Once again, under the lot and samples,
7 the first seven, those products are identical
8 except for the differences in coating or coating
9 concentration?

10 MR. BONELLA: Object to form.

11 A. That's how it looked like.

12 Q. Now, the next column where it says
13 overall knot strength, what is that referring to?

14 A. It is referring to the suture loop
15 with the several knots tied and then it is pulled
16 apart.

17 Q. Is there a standard knot strength
18 test?

19 MR. BONELLA: Object to form.

20 A. Standard where?

21 Q. Well, let me ask it, at Ethicon, does
22 Ethicon have a standardized knot strength test?

23 A. Yes.

24 Q. Are these results here, are the
25 results of that standardized knot strength test,

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

_____)	
DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
_____)	

**ARTHREX, INC.'S SECOND SUPPLEMENTAL OBJECTIONS AND RESPONSES
TO DEPUY MITEK, INC.'S INTERROGATORY NOS. 3, 5, AND 7 AND
ARTHREX'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO DEPUY
MITEK, INC.'S INTERROGATORY NO. 6**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant Arthrex, Inc., ("Arthrex") hereby provides second supplemental responses to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory Nos. 3, 5, and 7 of DePuy Mitek's First Set of Interrogatories and supplemental response to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory No. 6 of DePuy Mitek's First Set of Interrogatories. These supplemental responses are based on information reasonably available to Arthrex at the present time. Arthrex reserves the right to further supplement these responses when, and if, additional information becomes available, or known, to Arthrex. These interrogatories also remain premature to the extent that they

seek expert information. Such information will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order entered by the Court. Arthrex also reserves the right to object on any ground at any time to these Interrogatories. Arthrex further reserves the right to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

GENERAL OBJECTIONS

Arthrex incorporates herein the General Objections included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

DEFINITIONS

Arthrex incorporates herein the Definitions included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

ANSWERS AND SPECIFIC OBJECTIONS

The following Second Supplemental Responses to DePuy Mitek's Interrogatory Nos. 3, 5, and 7 and Supplemental Response to DePuy Mitek's Interrogatory No. 6 are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Response as though fully set forth therein. To the extent particular General Objections are restated in a Response, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

INTERROGATORY NO. 3.

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶ 12-13 of Arthrex's Answer including, but not limited to,

(a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;

(b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.

(c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and

(d) explain all facts that support any prosecution history estoppel contention with respect to the Patent-in-Suit including but not limited to the specific pages and lines of the prosecution history that Arthrex contends evidence prosecution history estoppel; and

(e) identify the tensile strength and bending strength and rigidity of each Arthrex Braided Suture Product with and without a coating and how those properties were determined and what samples were used in any such determination.

RESPONSE

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Arthrex Braided Suture Product" as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement allegations, or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order issued by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex's FiberWire® suture products do not contain any of the "first fiber-forming materials" recited in the claims of the '446 patent, as properly construed. Arthrex further answers that the '446 patent does not have any basic and novel characteristics. See, for example, Arthrex's Response to Interrogatory No. 5, which is

incorporated herein by reference. The '446 patent, however, purports to have at least one basic and novel characteristic of the alleged invention in that it claims to achieve certain results with only a combination of one of a listed first fiber-forming material and one of a listed second fiber-forming material. Even if the claims of the '446 patent were improperly construed to support a contention that the Arthrex FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent and Arthrex's FiberWire® suture products do not achieve the desired results without the coating. Arthrex also answers that at least for these reasons, its FiberWire® suture products do not infringe the claims of the '446 patent under the reverse doctrine of equivalents even if the claims could be construed to cover Arthrex's products.

Arthrex further answers that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as claimed in the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged invention defined by the claims of the '446 patent, as properly construed. Moreover, DePuy Mitek would be estopped from contending that there is infringement by the doctrine of equivalents for any limitation that was amended for reasons of patentability. *See e.g.*, Amendment dated August 4, 1993 in which claim 21 was amended from reciting "comprising" to "consisting essentially of." *See id.* in which specific fiber-forming materials for each set of yarns were added to claim 21.

Arthrex further answers that non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Such document(s) will include Arthrex's 510(k) submission to the U.S. Food and Drug Administration as well as various test reports.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that its FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

The fact that any mention of UHMWPE is absent from the '446 patent is also consistent with statements made by the applicants and their attorneys during prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent. For example, in distinguishing the alleged invention over Burgess (U.K. Patent Application No. 2,218,312A), the applicants and their attorneys stated that one would not be motivated to use UHMWPE, as disclosed in Burgess for suture applications. The applicants and their attorneys further stated that if one were to employ the teachings of references such as Burgess "to modify a suture, then he would inevitably design an unacceptable suture." Amendment dated August 6, 1992 at pages 2-4. DePuy Mitek cannot now recapture this subject matter that was so clearly disclaimed during prosecution of the '511 application. Accordingly, for this additional reason, the asserted claims of the '446 patent cannot be properly construed to include UHMWPE. Similarly, these actions constitute prosecution history estoppel.

The '446 patent describes the purported basic and novel characteristics of the invention. The purported basic and novel characteristics of the '446 patent appear to be enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent, as described above. That is, Arthrex's FiberWire® suture products, without coating, do not achieve the desired results --

enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Arthrex further responds that its FiberWire® suture products do not include first and second sets of continuous and discrete yarns where each of the discrete yarns is in a sterilized, braided construction, as required by the asserted claims because UHMWPE and PET are not braided before being combined with one another.

Arthrex also responds that its FiberWire® suture products do not include yarns from a first set and yarns from a second set, as required by the asserted claims because its FiberWire® suture products do not contain a yarn from the first set of yarns to provide pliability or a yarn from the second set of yarns to provide strength.

Arthrex further responds that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as the alleged invention of the asserted claims of the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged inventions of the asserted claims of the '446 patent. For example, Arthrex's FiberWire® suture products employ UHMWPE, a material not even considered viable for use in sutures by the applicants of the '446 patent and their attorneys -- for strength. To the contrary, for improved strength, the '446 patent discloses the use of, among other materials, PET -- a material which Arthrex's FiberWire® suture products employ for improving handling properties.

SECOND SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that its FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

Rather, the '446 patent discloses polyethylene ("PE") for use with its claimed suture. Had the inventors intended to include UHMWPE in its disclosure, it would have been specifically identified. Many other prior art patents to the '446 patent also disclosed PE for use with sutures – each of them meaning commodity PE and not UHMWPE. Some examples of such patents include U.S. Patent Nos. 3,939,969; 4,060,885; 4,142,628; 4,950,285; 5,080,667; 5,123,913; and 5,662,682. Likewise, prior art materials intending to disclose UHMWPE make a specific reference to UHMWPE and not PE. *See, e.g.*, U.K. Patent Application No. 2,218,312A, to Burgess ("Burgess"), the '575 patent, the DSM brochure entitled *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure") (Bates range PR 8420 to 8429), and Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture*, *Arch Ophthalmol* – Vol. 103, December 1985 ("the Cohan article") (Bates range ARM 25132 to 25137).

Furthermore, the specification of the '446 patent makes clear that the relatively weak commodity PE, rather than the ultra strong UHMWPE was intended by the inventors. For example, the specification explains that the relatively weak fibers of the first fiber-forming group are too weak to be used alone as sutures and warns that using greater than 80% of such fibers will adversely affect the overall strength of the braid. PE is included in the group of relatively weak materials.

Arthrex further responds that the '446 patent describes the purported basic and novel characteristics of the invention as improved handleability and pliability performance of the suture without significantly sacrificing its physical properties. It is well known that suture handleability includes, but is not limited to, any of the following suture characteristics: knot sliding, knot tie-down, feel, tissue sliding, knot security, ease of cutting, pliability, coefficient of friction, lubricity, stiffness, softness, smoothness, lack of chatter, and lie-down of the knot, many of which are specifically mentioned or implied in the specification and would be understood by one of ordinary

skill in the art. The specification explained that strength (e.g., tensile and knot strength) and knot security are the physical properties of a suture that should not be appreciably sacrificed. The '446 patent achieves these results without the use of coating. In fact, the specification of the '446 patent denigrates the use of coating.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both fiber-forming materials, as previously mentioned, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent. Arthrex's FiberWire® suture products use coating to improve the handleability of the suture without significantly sacrificing its physical properties. Such effects of coating on suture are well known in the art, are documented in U.S. patents, various materials produced by Arthrex and DePuy Mitek and in tests conducted by Arthrex. In addition, the coating affects the basic and novel characteristics of the '446 patent because the coating improves the knot strength of FiberWire suture.

Arthrex further responds that FiberWire sutures are sold with their ends tipped (*i.e.*, stiffened) to approximately 1 inch. The tipped ends are achieved by adding an adhesive material to the suture during processing. Tipping the ends of the suture make it easier for surgeons to thread the suture through surgical instruments, prevents fraying of the ends, and serves to restrict the fiber mobility of the first and second fiber forming materials and restricts the bendability of the tipped portion of the suture. Thus, the handleability is greatly improved over untipped suture.

Arthrex's FiberStick suture is a product that makes greater use of this adhesive material which affects the basic and novel characteristics of the '446 patent. FiberStick is stiffened to approximately 12-inches. The stiffened portion of FiberStick greatly improves handleability by easing passage of the suture through cannulated instruments and/or spinal needles and provides even greater restrictions of fiber mobility and bendability. The use of FiberStick also alleviates the need for monofilament or wire

suture shuttles. FiberStick also does not infringe the '446 patent for all the reasons discussed in connection with FiberWire in this answer and its supplements.

In addition to the non-infringement reasons discussed in connection with FiberWire in this answer and its supplements, Arthrex further states that its TigerWire suture includes UHMWPE, PET and nylon. Among other things, adding nylon to the suture increases stiffness (*i.e.*, less pliable) and improves the strength of the suture. Thus, the nylon added to the suture affects the alleged basic and novel characteristics of the '446 patent.

INTERROGATORY NO. 5.

To the extent that Arthrex contends that any claim of the Hunter patent is invalid under 35 U.S.C. § 102 or 103 (Answer at ¶¶ 9, 10):

(a) identify each item of prior art upon which Arthrex relies, and make an element-by-element application (providing specific citation to the relevant portions of the prior art) of each allegedly invalid claim to each item of prior art, explaining in detail the grounds for any allegation of invalidity under 35 U.S.C. § 102; and

(b) state the factual basis for any contention that any claim of the Patent-in-Suit is invalid under 35 U.S.C. § 103, including specifically, Arthrex's contentions of the level of ordinary skill in the art, the similarities and differences between each item of prior art and each claim, the scope and content of the prior art, and any secondary considerations.

RESPONSE

Arthrex objects to this Interrogatory as being vague and ambiguous to the extent it refers to "the Hunter patent," which is an undefined term. To the extent "the Hunter patent" refers to the '446 patent, Arthrex also objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting,

example, Burgess in view of either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"). Both of the Harpell patents disclose the use of UHMWPE in surgical suture applications. Had the Examiner known of the Harpell patents in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the Harpell patents in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

INTERROGATORY NO. 6.

With respect to Arthrex's inequitable conduct defense and counterclaim:

- (a) identify all persons who allegedly committed inequitable conduct;
- (b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and
- (c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

RESPONSE

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Most of the facts surrounding the alleged inequitable conduct are known to the applicants of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, and their attorneys; and since discovery has

only just begun in this case, Arthrex has not yet had an opportunity to obtain all information responsive to this Interrogatory. Subject to and without waiving its general and specific objections, Arthrex answers:

(a) At least the applicants of the '511 application and their attorneys, including Hal Brent Woodrow, committed the alleged inequitable conduct.

(b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." See Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id.*

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments *having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable.*" [Emphasis added.] Kaplan at column 9, lines 25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." See Amendment

filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that during the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (*e.g.*, poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys truly believed that high tensile polythene was included within their claimed invention, then they could not have honestly made these statements and representations to the examiner. Accordingly, in such circumstances, the applicants and their attorney made a material misstatement with intent to deceive the PTO.

INTERROGATORY NO. 7.

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative defenses ¶11):

(a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. § 112; and

CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7 and Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6 has been served by facsimile on the following counsel for DePuy Mitek, Inc. on this 27th day of January 2006:

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s/Salvatore P. Tamburo
Salvatore P. Tamburo

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

_____)	
DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
_____)	

**PEARSALLS, LIMITED'S OBJECTIONS AND ANSWERS TO DEPUY MITEK,
INC.'S FIRST SET OF INTERROGATORIES TO PEARSALES LIMITED**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant Pearsalls, Limited ("Pearsalls") hereby responds to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek") First Set of Interrogatories. These responses are based on information reasonably available to Pearsalls at the present time. Pearsalls reserves the right to supplement these responses when, and if, additional information becomes available. Pearsalls also reserves the right to object on any ground at any time to these Interrogatories. These interrogatories also remain premature to the extent that they seek expert information. Such information will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order entered by the Court. Pearsalls further reserves the right

to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

GENERAL OBJECTIONS

Pearsalls incorporates herein its Objections to the Definitions included in its Objections and Responses to DePuy Mitek's First Set of Requests for Documents and Things to Pearsalls, Ltd. as if fully set forth herein.

ANSWERS AND SPECIFIC OBJECTIONS

The following Answers to DePuy Mitek's Interrogatories are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Answer as though fully set forth therein. To the extent particular General Objections are restated in an Answer, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

INTERROGATORY NO. 1.

Describe all facts that support Pearsalls' contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶17-18 of Pearsalls' Answer including, but not limited to,

(a) identifying each element of each claim of the Patent-in-Suit that Pearsalls contends is literally absent from each Braided Suture Product;

(b) explain (i) what Pearsalls contends the basis and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Pearsalls does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Pearsalls' Braided Suture Products.

(c) explain any Pearsalls contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Pearsalls Braided Suture Products and any reason why the function/way/result test is not satisfied for each Pearsalls Braided Suture Product; and

(d) explain all facts that support any prosecution history estoppel contention with respect to the Patent-in-Suit including but not limited to the specific pages and lines of the prosecution history that Pearsalls contends evidence prosecution history estoppel; and

(e) identify the tensile strength and bending strength and rigidity of each Pearsalls Braided Suture Product with and without a coating and how those properties were determined and what samples were used in any such determination.

RESPONSE

Pearsalls objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Arthrex Braided Suture Product" as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Pearsalls further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order issued by the Court. Subject to and without waiving its general and specific objections, Pearsalls answers:

Pearsalls does not manufacture a sterilized surgical suture as required by claim 1 of the '446 patent. Rather, Pearsalls manufactures braids. DePuy Mitek has failed to meet its burden to prove that the braids manufactured by Pearsalls are a material part of the alleged invention of the '446 patent. DePuy Mitek has also failed to meet its burden to prove that Pearsalls knows its braids are specifically made or adapted for use in an alleged infringement of the alleged invention of the '446 patent. DePuy Mitek has also failed to meet its burden to prove that Pearsalls's braids are not a staple article of commerce suitable for substantial non-infringing use. Further, since there is no direct infringement of the '446 patent, there can be no indirect infringement.

Arthrex's FiberWire® suture products do not contain any of the "first fiber-forming materials" recited in the claims of the '446 patent, as properly construed. Pearsalls further answers that the '446 patent does not have any basic and novel characteristics. The '446 patent, however, purports to have at least one basic and novel characteristic of the alleged invention in that it claims to achieve certain results with only a combination of one of a listed first fiber-forming material and one of a listed second fiber-forming material. Even if the claims of the '446 patent were improperly construed to support a contention that the Arthrex FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent and Arthrex's FiberWire® suture products do not achieve the desired results without the coating. Pearsalls also answers that at least for these reasons, Arthrex's FiberWire® suture products do not infringe the claims of the '446 patent under the reverse doctrine of equivalents even if the claims could be construed to cover Arthrex's products.

Arthrex further answers that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as claimed in the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged invention defined by the claims of the '446 patent, as properly construed. Moreover, DePuy Mitek would be estopped from contending that there is infringement by the doctrine of equivalents for any limitation that was amended for reasons of patentability. *See e.g.*, Amendment dated August 4, 1993 in which claim 21 was amended from reciting "comprising" to "consisting essentially of." *See id.* in which specific fiber-forming materials for each set of yarns were added to claim 21.

Pearsalls further answers that non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained have been

produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Such document(s) included Arthrex's 510(k) submission to the U.S. Food and Drug Administration as well as various test reports.

In addition to the above, Pearsalls further responds that Arthrex's FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

The fact that any mention of UHMWPE is absent from the '446 patent is also consistent with statements made by the applicants and their attorneys during prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent. For example, in distinguishing the alleged invention over Burgess (U.K. Patent Application No. 2,218,312A), the applicants and their attorneys stated that one would not be motivated to use UHMWPE, as disclosed in Burgess for suture applications. The applicants and their attorneys further stated that if one were to employ the teachings of references such as Burgess "to modify a suture, then he would inevitably design an unacceptable suture." Amendment dated August 6, 1992 at pages 2-4. DePuy Mitek cannot now recapture this subject matter that was so clearly disclaimed during prosecution of the '511 application. Accordingly, for this additional reason, the asserted claims of the '446 patent cannot be properly construed to include UHMWPE. Similarly, these actions constitute prosecution history estoppel.

The '446 patent describes the purported basic and novel characteristics of the invention. The purported basic and novel characteristics of the '446 patent appear to be enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged

basic and novel characteristics of the '446 patent, as described above. That is, Arthrex's FiberWire® suture products, without coating, do not achieve the desired results -- enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Pearsalls further responds that Arthrex's FiberWire® suture products do not include first and second sets of continuous and discrete yarns where each of the discrete yarns is in a sterilized, braided construction, as required by the asserted claims because UHMWPE and PET are not braided before being combined with one another.

Pearsalls also responds that Arthrex's FiberWire® suture products do not include yarns from a first set and yarns from a second set, as required by the asserted claims because Arthrex's FiberWire® suture products do not contain a yarn from the first set of yarns to provide pliability or a yarn from the second set of yarns to provide strength.

Pearsalls further responds that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as the alleged invention of the asserted claims of the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged inventions of the asserted claims of the '446 patent. For example, Arthrex's FiberWire® suture products employ UHMWPE, a material not even considered viable for use in sutures by the applicants of the '446 patent and their attorneys -- for strength. To the contrary, for improved strength, the '446 patent discloses the use of, among other materials, PET -- a material which Arthrex's FiberWire® suture products employ for improving handling properties.

In addition to the above, Pearsalls further responds that Arthrex's FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a

material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

Rather, the '446 patent discloses polyethylene ("PE") for use with its claimed suture. Had the inventors intended to include UHMWPE in its disclosure, it would have been specifically identified. Many other prior art patents to the '446 patent also disclosed PE for use with sutures – each of them meaning commodity PE and not UHMWPE. Some examples of such patents include U.S. Patent Nos. 3,939,969; 4,060,885; 4,142,628; 4,950,285; 5,080,667; 5,123,913; and 5,662,682. Likewise, prior art materials intending to disclose UHMWPE make a specific reference to UHMWPE and not PE. *See, e.g.*, U.K. Patent Application No. 2,218,312A, to Burgess ("Burgess"), the '575 patent, the DSM brochure entitled *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure") (Bates range PR 8420 to 8429), and Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture*, Arch Ophthalmol – Vol. 103, December 1985 ("the Cohan article") (Bates range ARM 25132 to 25137).

Furthermore, the specification of the '446 patent makes clear that the relatively weak commodity PE, rather than the ultra strong UHMWPE was intended by the inventors. For example, the specification explains that the relatively weak fibers of the first fiber-forming group are too weak to be used alone as sutures and warns that using greater than 80% of such fibers will adversely affect the overall strength of the braid. PE is included in the group of relatively weak materials.

Pearsalls further responds that the '446 patent describes the purported basic and novel characteristics of the invention as improved handleability and pliability performance of the suture without significantly sacrificing its physical properties. It is well known that suture handleability includes, but is not limited to, any of the following suture characteristics: knot sliding, knot tie-down, feel, tissue sliding, knot security, ease of cutting, pliability, coefficient of friction, lubricity, stiffness, softness,

smoothness, lack of chatter, and lie-down of the knot, many of which are specifically mentioned or implied in the specification and would be understood by one of ordinary skill in the art. The specification explained that strength (e.g., tensile and knot strength) and knot security are the physical properties of a suture that should not be appreciably sacrificed. The '446 patent achieves these results without the use of coating. In fact, the specification of the '446 patent denigrates the use of coating.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both fiber-forming materials, as previously mentioned, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent. Arthrex's FiberWire® suture products use coating to improve the handleability of the suture without significantly sacrificing its physical properties. Such effects of coating on suture are well known in the art, are documented in U.S. patents, various materials produced by Arthrex and DePuy Mitek and in tests conducted by Arthrex. In addition, the coating affects the basic and novel characteristics of the '446 patent because the coating improves the knot strength of FiberWire suture.

Pearsalls further responds that FiberWire sutures are sold with their ends tipped (*i.e.*, stiffened) to approximately 1 inch. The tipped ends are achieved by adding an adhesive material to the suture during processing. Tipping the ends of the suture make it easier for surgeons to thread the suture through surgical instruments, prevents fraying of the ends, and serves to restrict the fiber mobility of the first and second fiber forming materials and restricts the bendability of the tipped portion of the suture. Thus, the handleability is greatly improved over untipped suture.

Arthrex's FiberStick suture is a product that makes greater use of this adhesive material which affects the basic and novel characteristics of the '446 patent. FiberStick is stiffened to approximately 12-inches. The stiffened portion of FiberStick greatly improves handleability by easing passage of the suture through cannulated instruments

and/or spinal needles and provides even greater restrictions of fiber mobility and bendability. The use of FiberStick also alleviates the need for monofilament or wire suture shuttles. FiberStick also does not infringe the '446 patent for all the reasons discussed in connection with FiberWire in this answer and its supplements.

In addition to the non-infringement reasons discussed in connection with FiberWire in this answer and its supplements, Pearsalls further states that Arthrex's TigerWire suture includes UHMWPE, PET and nylon. Among other things, adding nylon to the suture affects its stiffness (*i.e.*, pliability) and affects the strength of the suture. Thus, the nylon added to the suture affects the alleged basic and novel characteristics of the '446 patent.

INTERROGATORY NO. 2.

To the extent that Pearsalls contends that any claim of the Hunter patent is invalid under 35 U.S.C. § 102 or 103 (Answer at ¶¶14 and 15):

- (a) identify each item of prior art upon which Pearsalls relies, and make an element-by-element application (providing specific citation to the relevant portions of the prior art) of each allegedly invalid claim to each item of prior art, explaining in detail the grounds for any allegation of invalidity under 35 U.S.C. § 102; and
- (b) state the factual basis for any contention that any claim of the Patent-in-Suit is invalid under 35 U.S.C. § 103, including specifically, Pearsalls' contentions of the level of ordinary skill in the art, the similarities and differences between each item of prior art and each claim, the scope and content of the prior art, and any secondary considerations.

RESPONSE

Pearsalls objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case

materials of claim 1 of the '446 patent, and the disclosed polyester is a second fiber forming material of claim 1. PET, as recited in claim 8, is a polyester, as disclosed in the '495 patent. The combined materials are manufactured in the core to be in direct intertwining contact with each other.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over the '495 patent in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

Pearsalls also responds that claims 1 and 8 of the '446 patent are invalid under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,234,006 ("the '006 patent"). The '006 patent discloses adjustable sutures made from combinations of polyethylene and polyesters. '006 patent at col. 3, lines 55-68. The disclosed polyethylene is a first fiber forming material of claim 1 of the '446 patent, and the disclosed polyester is a second fiber forming material of claim 1. PET, as recited in claim 8, is a polyester, as disclosed in the '006 patent. The combined materials are manufactured to be in direct intertwining contact with each other.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over the '006 patent in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

INTERROGATORY NO. 3.

With respect to Pearsalls' inequitable conduct defense:

- (a) identify all persons who allegedly committed inequitable conduct;

- (b) state all facts supporting Pearsalls' contention that the such persons committed inequitable conduct; and
- (c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

RESPONSE

Subject to and without waiving its general objections, Pearsalls answers:

- (a) At least the applicants of the '511 application and their attorneys, including Hal Brent Woodrow, committed the alleged inequitable conduct.
- (b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." See Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id.*

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments *having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable.*" [Emphasis added.] Kaplan at column 9, lines

25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." See Amendment filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

In addition to the above, Pearsalls further responds that during the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (*e.g.*, poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys truly believed that high tensile polythene was included within their claimed invention, then they could not have honestly made these statements and representations to the examiner. Accordingly, in such circumstances, the applicants and their attorney made a material misstatement with intent to deceive the PTO.

INTERROGATORY NO. 4.

With respect to Pearsalls' contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative Defenses ¶16):

CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Pearsalls, Limited's Objections and Answers to DePuy Mitek, Inc.'s First Set of Interrogatories to Pearsalls, Limited has been served by facsimile on the following counsel for DePuy Mitek, Inc. on this 27th day of January 2006:

Lynn A. Malinoski
Woodcock Washburn, LLP
One Liberty Place, 46th Floor
Philadelphia, PA. 19103

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604

s/Salvatore P. Tamburo
Salvatore P. Tamburo

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF JOHN F. WITHERSPOON

INTRODUCTION

I have been asked by counsel for defendant Arthrex, Inc. ("Arthrex") to serve as an expert consultant with respect to United States patent practices and procedures, both generally and as they relate to this case, and on various issues in the case. I understand that I may be called to present expert testimony at trial, including testimony in rebuttal, and I have been asked to prepare a written report with respect to that possible testimony. More specifically, I have been asked at this time to prepare a report setting forth (a) a general description of United States Patent and Trademark Office ("PTO") practices and procedures, (b) a discussion of the prosecution history of United States Patent No. 5,314,446 ("the '446 patent") here in suit, and (c) opinions specific to this case regarding certain issues for which Arthrex has the burden of proof.

27. 37 CFR § 1.56 (1992), commonly referred to as PTO “Rule 56,” reads in part as follows:

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section...

28. Examiners expect and rely on inventors and their attorneys or agents to be truthful and to act with candor and good faith in dealing with the PTO, as required by the PTO regulations and case decisions. The duty applies to all individuals associated with the filing or prosecution of an application. These individuals have a duty to disclose information known to one or more of them to be material to patentability. Examiners expect and rely on them to comply with this duty. There are several reasons for these expectations. First, as discussed above, an examiner does not have access to all prior art. Nor does an examiner have an opportunity to verify the accuracy of representations of fact known only by the inventor. Second, an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, may mislead an examiner into granting a patent which does not meet the legal criteria. The duty of disclosure includes a duty to tell an examiner of an erroneous material representation, when discovered, during PTO proceeding.

29. Normally material prior art is called to an examiner’s attention by filing a document known as an Information Disclosure Statement (“IDS”). However, such

information may also be called to an examiner's attention in the remarks section of a response to an Office Action or in the patent application itself.

30. Prior to March 16, 1992, Rule 56 defined material information as information as to which there is a substantial likelihood a reasonable examiner would consider the information important in deciding whether to allow the application. Since March 16, 1992, Rule 56 has provided that information is material when it is not cumulative to information already of record and (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) refutes, or is inconsistent with, a position the applicant takes in either opposing an argument of unpatentability or asserting an argument of patentability.

31. The MPEP is an official publication of the PTO that is intended to provide patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the PTO. Section 2004, entitled "Aids to Compliance With Duty of Disclosure" sets forth suggestions for complying with the duty of disclosure. Among things to be considered are: "the origin of the invention and its point of departure from what was previously known and in the prior art;" "possible public uses and sales;" and "prior publication, knowledge, patents, foreign patents, etc." Section 2004 also emphasizes that "[c]are should be taken to see that prior art or other information cited in a specification or an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized." It is further pointed out that "[w]hen in doubt, it is desirable and safest to submit information," since "[e]ven though the attorney, agent, or applicant doesn't consider it necessarily material, someone

else may see it differently and embarrassing questions can be avoided.” In this regard, the Manual points out that one district court has stated: “In short, the question of relevancy in close cases, should be left to the examiner and not the applicant.” The Manual also notes that “[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention.” Thus the MPEP strongly suggests erring on the side of disclosure. (The quoted passages from the MPEP appeared in the Manual throughout the pendency of the application leading to the ‘446 patent.)

32. The duty of inventors and their attorneys or agents to disclose material information is a continuing duty that runs throughout the entire pendency of a patent application.

33. In reviewing an application, an examiner is expected to determine whether the specification contains a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which the invention pertains to make and use the invention without undue experimentation. To the extent possible, he or she also reviews the application to see whether the best mode contemplated by the inventor of carrying out her invention is disclosed. These requirements are sometimes called (1) the “written description” requirement, (2) the “enablement” requirement, and (3) the “best mode” requirement.

34. An examiner is expected to understand that the test for the written description requirement is whether the disclosure of the application reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time the application was filed and that the test for the enablement requirement is whether the

perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

61. In responding to this rejection, Mr. Goodwin represented to the examiner that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester, then “he would inevitably design an unacceptable suture.” In his response, Mr. Goodwin also represented to the examiner that the braided combination disclosed in Burgess would have “poor knot strength properties.”

62. Dr. Steckel’s testimony regarding the use of UHMWPE in a braided suture is the opposite of what Mr. Goodwin represented to the examiner. Dr. Steckel also testified that he and Mr. Hunter discussed braiding UHMWPE and polyester prior to the filing date of the ‘511 application and that they believed it would lead to an acceptable suture. Further, Dr. Steckel testified that at the time he considered such a combination to be “a good idea” and that braiding UHMWPE and polyester together would result in “improved knot strength.”

63. In my opinion, the arguments presented to the examiner with respect to alleged distinctions between the claimed invention (assuming the claims include UHMWPE) and Burgess are inconsistent with Dr. Steckel’s testimony. It is also my opinion that, accepting Dr. Steckel’s testimony as true, the representations made to the examiner are misrepresentations in highly material respects, because they were made for the purpose of overcoming a prior art rejection in order to obtain the allowance of claims for issuance in a patent.

EXHIBIT 17

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

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IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts)
Corporation,)
Plaintiff,)
v.)
ARTHREX, INC., a Delaware)
Corporation,)
Defendant.)

Civil Action
No. 04-12457 PBS

COPY

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

HIGHLY
CONFIDENTIAL

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

1 samples 100% -- you see later down in the letter it
2 says:

3 "Can you build a 25% Dyneema/75%
4 polyester blend in a size 2 that is very flexible
5 (like the existing suture or the ethicon sample) and
6 send it to me to test".

7 Do you see that?

8 A Yes.

9 Q In the top paragraph does the sample of
10 the Dyneema material, does that refer to a braid of
11 100% Dyneema?

12 A I can't remember.

13 Q Do you recall ever making a construction
14 that was 100% ultra high molecular weight
15 polyethylene for Arthrex?

16 A I can't remember.

17 Q In November '98 is that when FiberWire was
18 first being developed?

19 A Yes.

20 Q What did you understand Mr. Grafton to
21 mean when he said:

22 "Can you build a 25% Dyneema/75%
23 polyester blend in Size 2 that is very flexible".

24 What did you understand that to mean?

25 A Yes, that he wanted a braid which was

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

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1 more -- not so stiff.

2 Q As the 100% ultra high molecular weight
3 polyethylene?

4 A Yes.

5 Q He wanted Pearsalls to try to put
6 polyester with --

7 A With the mixture.

8 Q With a braid. He wanted -- let me finish
9 the question before you answer.

10 Mr. Grafton wanted Pearsalls to braid
11 polyester with the ultra high molecular weight
12 polyethylene so that the polyester could provide
13 flexibility?

14 A Yes.

15 Q Next I will show you Exhibit 325. It is
16 Bates number PR 6493. Do you recognize Exhibit 325
17 as a letter from you to Mr. Grafton from November
18 1998?

19 (DePuy Mitek Exhibit 325 marked for identification)

20 A Yes.

21 Q And the letter said:

22 "Please find enclosed a matrix of
23 information of the samples that you took with you on
24 your visit to Pearsalls, I will endeavour to proceed
25 with the existing trial to match US2 Excel Braid

EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF JOHN F. WITHERSPOON

I am the same John F. Witherspoon who submitted expert reports in this litigation on March 3, 2006 and March 24, 2006, which reports I incorporate herein by reference. I have reviewed the expert report of Dr. Matthew Hermes and I submit this report in response to aspects of Dr. Hermes' report that relate to patent practices and procedures, including his reply to certain opinions set forth in my March 3 report. I have also reviewed the Rebuttal Expert Report of Dr. Debi Prasad Mukherjee, as well as the transcript of the deposition of Donald Grafton given on March 14, 2006.

I.

1. I do not fully understand the significance of the attempt to distinguish between "a person of ordinary skill in the art" and "a person of skill in the art" in paragraph 31 of the Hermes report, because this seems to suggest that the level of skill of the persons referenced in sections 103 and 112 of the statute is not the same. I am not aware of any authority in support of this position.

- Q. You thought it was a good idea?
- A. We thought we could have improved knot strength, and we could get the beneficial properties of both in a blend. That's what we thought.

Thus, according to Dr. Steckel, before filing their application in the PTO the applicants believed that a braided structure of Dyneema and PET (a polyester) could have good knot characteristics. They believed that this combination could lead to an acceptable suture.

7. During prosecution of their application, however, when faced with a rejection based on a prior art disclosure (Burgess) of a fishing line having a braided structure of a high molecular weight polyethylene, Dyneema being specifically named, with polyester and/or nylon, the applicants tried to convince the examiner that their braid was patentable over the braid of the fishing line by making the following representations (Amendment mailed August 4, 1982) (all emphases in original):

In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below: (Page 2)

Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security. (Page 3)

Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture. (Pages 3-4)

The examiner's rejection on Burgess was then dropped, which the applicants acknowledged with gratitude.

8. In my opinion, the statements made to the examiner are not consistent with Dr. Steckel's testimony. On the one hand, according to Dr. Steckel, he and Mr. Hunter believed that a braid of Dyneema and PET could provide an acceptable suture with improved knot strength characteristics; on the other hand, they told the examiner that the

Burgess braid would have poor knot strength properties. It is also my opinion that the statements made to the examiner are affirmative misrepresentations, if the applicants believed that their claims included braids of Dyneema and PET. And they are highly material misrepresentations, because they were made in an attempt to overcome a rejection based on a very close prior art reference, which attempt turned out to be successful.

9. Dr. Hermes has four responses to my opinion. First, he says that in my earlier report I failed to include the words “the teachings of the fishing line art” in the last of the three quotations set forth above. I do not understand his point. My earlier discussion was clearly referring to the fishing line art as disclosed in Burgess, namely a fishing line of a braid having Dyneema filaments and filaments of polyester and/or nylon. In any event, I have now included the words in the quotation above, and my opinion remains the same. Second, Dr. Hermes says he is not clear what statements by Dr. Steckel I have in mind. The statements are easily found in the transcript and they are set forth above. Third, Dr. Hermes says that Dr. Steckel’s testimony is not inconsistent with the attorney’s statements. As already indicated, I very much disagree. Dr. Steckel testified that he and Mr. Hunter believed that the combination of Dyneema and a polyester could lead to an acceptable suture with improved knot strength. Mr. Goodwin represented the opposite in the applicants’ successful attempt to overcome prior art. A braid that could lead to an acceptable suture with improved knot strength does not become otherwise by calling it a fishing line. Fourth, Dr. Hermes says that nothing was withheld from the examiner because the application of the ‘446 patent “discloses ultra high molecular weight polyethylene, UHMWPE.” Dr. Mukherjee does not agree. In any

event, I fail to find any mention of the terms “Dyneema,” “Spectra,” “ultra high molecular weight polyethylene,” or “UHMWPE” anywhere in the ‘446 patent. (Nor, incidentally, do I find any of this terminology anywhere in Dr. Steckel’s notebooks that I reviewed.) In my opinion, no reasonable examiner would have dropped a rejection based on Burgess if she believed that the applicants’ claims included a braid of Dyneema and PET, based on the arguments made by the applicants. Many of the attorney’s arguments would have been irrelevant, since the claims do not recite such properties as elongation and knot strength and security, upon which to distinguish the disclosure of Burgess. In my opinion, the examiner here must have believed that the claims did not include braids of Dyneema and PET.

April 13, 2006


John F. Witherspoon

EXHIBIT 19



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.
 Serial No.: 838,511 ✓ Art Unit: 1504
 Filed : February 19, 1992 ✓ Examiner: C. Raimund
 For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992
 (Date of Deposit)

Matthew S. Goodwin
 Name of applicant, assignee, or Registered Representative

Matthew S. Goodwin
 (Signature)

DEC 10 1992

December 2, 1992
 (Date of Signature)

GROUP 1500

Hon. Commissioner of Patents
 and Trademarks
 Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No.04-12457 PBS
 DMI000235

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

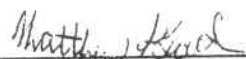
3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

EXHIBIT 20

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COPY

DEPUY MITEK, INC., a Massachusetts)
Corporation,)
Plaintiff,) Civil Action
v.) No. 04-12457 PBS
ARTHREX, INC., a Delaware)
Corporation,)
PEARSALLS LTD., a Private Limited)
Company of the United Kingdom,)
Defendants.)

- - - - -

VIDEO DEPOSITION OF JOHN WITHERSPOON

Washington, D.C.

Tuesday, June 20, 2006

The videotaped deposition of JOHN WITHERSPOON was
convened on Tuesday, June 20, 2006, commencing at
9:03 a.m., at the offices of Dickstein Shapiro Morin
& Oshinsky LLP, 2101 L Street, Northwest,
Washington, D.C., before Cynthia R. Simmons Ott,
Registered Merit Reporter, Certified Realtime
Reporter, and Notary Public.

1 A. Correct.

2 Q. And it's not uncommon for a patent
3 applicant to amend his claims in response to an
4 office action rejecting his claims?

5 A. Correct.

6 Q. You're not testifying or planning to
7 testify in this case that the inventors, or the
8 attorneys who were involved in prosecuting the
9 Hunter patent, withheld any material prior art,
10 is that right?

11 A. As opposed to material information
12 that is not prior art necessarily.

13 Q. Right.

14 A. I think that's right.

15 Q. In paragraph 30 of your report, which
16 is on page 12, you make note of two standards
17 for materiality in Rule 56?

18 A. Yes.

19 Q. A prior one and a more current one?

20 A. Yes.

21 Q. Did you apply one of those standards
22 in forming your opinion?

23 A. Which opinion are you referring to in
24 your question?

25 Q. Well, did you form an opinion with

1 respect to the materiality of a representation
2 made by Attorney Goodwin to the Patent Office
3 during prosecution of the Hunter patent?

4 A. Well, I formed an opinion that the
5 representations made by counsel to the examiner
6 with respect to an effort which was successful
7 in getting rid of a rejection based on Burgess,
8 and statements made by Dr. Steckel in his
9 deposition, are not consistent.

10 So you could look at it either of two
11 ways. That the statements by the attorney
12 should not have been made, that those are
13 material because they're inconsistent with the
14 facts as testified to by Dr. Steckel, or that
15 if they were made, there was material
16 information withheld, namely the information
17 that Dr. Steckel testified to. Either way,
18 when you look at the situation from the
19 standpoint of the examiner examining the case,
20 the examiner didn't have the full story.

21 Q. Do you plan to testify that material
22 information was withheld from the examiner?

23 A. Well, you know, obviously, I don't
24 know what questions I'll be asked. But if
25 asked, I would so testify.

1 Q. And what material information would
2 you testify was withheld from the examiner?

3 MR. SABER: Objection, asked and
4 answered.

5 THE WITNESS: That Dr. Steckel and --
6 at least Dr. Steckel, and perhaps Mr. Hunter as
7 well, believed back in 1988 or '89 that a braid
8 made of Spectra, an ultra high molecular weight
9 polyethylene and polyethylene terephthalate,
10 PET, could provide a successful suture, could
11 provide a braid which could be converted into a
12 successful suture.

13 BY MS. ELDERKIN:

14 Q. And it's your opinion that that was a
15 material bit of information for the examiner?

16 A. Yes, because contrary information was
17 being told to the examiner. Absent the
18 contrary information, then I would not consider
19 this information to be material. But it's
20 material because it is inconsistent with what
21 had been told to the examiner.

22 Q. Okay. And which of the tests for
23 materiality are you applying in arriving at
24 that conclusion?

25 A. Either one.

1 there is nothing on this record to show them to
2 be obvious variants.

3 Now, that's what the examiner says,
4 but I would point out that all this discussion
5 is in the context of making a restriction
6 requirement. And words like patentably
7 distinct and so on mean that you are entitled
8 to those claims in another patent, at least
9 you're entitled to prosecute them in another
10 patent.

11 We should keep in mind that this is
12 not a discussion of obviousness in the sense of
13 103, however. This is an implementation of the
14 Commissioner's instructions about how the
15 Commissioner wants to take advantage and
16 implement the authorization he gets in 121
17 about requiring restrictions. And you see the
18 several citations, in fact, to the MPEP.

19 Q. Isn't it the case, though, in the
20 context of this restriction requirement, the
21 examiner said that "an intermediate product
22 useful as a fishing line," and the inventions
23 are deemed patentably distinct?

24 MR. SABER: Objection, vague, the
25 words speak for themselves. He's not here just

1 A. Unexpected. Well, that's -- what I
2 said seems to me is equitable in part for all
3 these factors. The short answer is, no, I did
4 not look at each of the -- of the secondary
5 considerations, and undertake an evaluation as
6 to whether they're entitled to too much weight.

7 Q. In paragraph 58 of your first report,
8 you begin a discussion that proceeds for
9 several paragraphs about whether Dr. Steckel,
10 Mr. Hunter and/or Mr. Goodwin may have violated
11 their duty to disclose material information to
12 the Patent Office.

13 And I note that in that first sentence
14 in paragraph 58, you say that "you expect to
15 testify that these gentlemen may have violated
16 their duty to disclose material information to
17 the PTO." And I note the language may have
18 violated. Do you intend to testify that they
19 did violate their duty to disclose material, or
20 that they may have violated their duty to
21 disclose material information?

22 A. Well, I don't know quite how to answer
23 that, other than that it depends upon how the
24 evidence at trial comes to -- comes in. And I
25 say that because there's some additional

185
1 information that I think needs to be found, for
2 which I don't have access now, that would bear
3 on whether there was a violation or not.

4 And that turns on answers to the
5 question of who knew what when. At this point
6 in time, there's some circumstantial evidence
7 that suggests that Mr. Steckel was aware of
8 what the patent examiner had been told, but I
9 can't point to a particular document or a piece
10 of testimony that clearly establishes that.
11 That's the reason for the use of the word may.

12 In other words, there's a lot of
13 information that indicates to me that there may
14 have been a violation here, and this isn't just
15 pulled out of thin air. But at this point in
16 time, I could not specifically say what
17 Dr. Steckel knew when, or what Mr. Goodwin knew
18 when, or Mr. Hunter knew when. But there's
19 evidence from which one could infer that they
20 knew.

21 Q. And without evidence, without
22 knowledge of what they knew, you cannot
23 conclude that any of those gentlemen violated
24 their duty of disclosure?

25 MR. SABER: Objection, misstates the

1 testimony.

2 THE WITNESS: Could you read that
3 back, please?

4 BY MS. ELDERKIN:

5 Q. And without knowledge of what those
6 gentlemen knew, and when they knew it, you
7 cannot conclude that any of them violated their
8 duty of disclosure?

9 MR. SABER: Same objection, misstates
10 the testimony, inconsistent with his testimony.

11 THE WITNESS: Well, no, I stand by the
12 statement that I've made here, that they may
13 have violated their duty. And I have referred
14 to the deposition testimony of Dr. Steckel and
15 Mr. Goodwin. But I would be -- I would not be
16 inclined, at this point, to say that they, in
17 fact, did violate it, knowing only what I know
18 now.

19 But I could say that it could well be
20 a very -- there's a very good chance that they
21 did, one or the other. And I'm thinking in
22 particular -- well, any of the three. Goodwin,
23 as I recall, said that Dr. Steckel was the
24 point man or the person he interacted with,
25 particularly with respect to preparing the

1 application and prosecuting it early on, which
2 suggests to me that Dr. Steckel and Mr. Goodwin
3 had a lot of information in common.

4 And if we believe Dr. Steckel's
5 testimony, which I'm prepared to accept, we
6 have all this Spectra and PET activity and
7 thought patterns and so on, that that's what
8 they thought could produce a good suture. And
9 this was well before the patent application was
10 filed.

11 And Goodwin worked with him in
12 preparing the patent application. It seems odd
13 to me that that kind of information would not
14 have been communicated to Mr. Goodwin. The
15 kinds of things he said in his deposition that
16 he knew all about, and was talking to Hunter
17 about. And yet you don't see boo in the patent
18 application about Spectra or Dyneema or ultra
19 high molecular weight polyethylene.

20 It's another reason that suggests to
21 me that that wasn't contemplated when this
22 patent application was written. Just PE and
23 now even though this is a hot number, this
24 Spectra stuff, why wouldn't it have been
25 mentioned in the patent application. It just

1 doesn't add up.

2 And if -- and then Goodwin goes off,
3 he either wasn't -- it seems to me he either
4 wasn't told that we're talking about ultra high
5 molecular weight polyethylene here when he was
6 writing up this patent application, or he was
7 told and deliberately misled the examiner when
8 it came to talking about Burgess. I don't see
9 how both of those can be -- can be reconciled.

10 Q. You considered the Burgess disclosure,
11 right, you refer to it in paragraph 60 of your
12 report?

13 A. Yes.

14 Q. Let me give you a copy of that. And
15 again, sorry, we just have the one copy here.
16 Let's put an exhibit sticker on there. We'll
17 mark as DePuy Mitek Exhibit 379, a copy of UK
18 patent application 2,218,312.

19 MR. SABER: It's 379.

20 MS. ELDERKIN: 379, yes.

21 (DePuy Mitek Exhibit Number 379 was
22 marked for identification.)

23 BY MS. ELDERKIN:

24 Q. So again, you refer to some
25 disclosures in the Burgess patent in paragraph

EXHIBIT 21

Deposition of:
Matthew Goodwin

January 17, 2006

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UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

-----x

ORIGINAL

DePUY MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

v.

ARTHREX INC.,

A Delaware Corporation,

Defendants.

-----x

DEPOSITION OF MATTHEW GOODWIN

New Brunswick, New Jersey

January 17, 2006

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO.: SE 173

1 GOODWIN

2 Jamialkowski?

3 A. Yes, I do.

4 Q. He was originally an inventor on this
5 application, the application which eventually
6 became Exhibit 10, is that correct?

7 A. I don't remember.

8 Q. Was there a main contact that you had
9 with one of the inventors or more than one of the
10 inventors in discussing this invention?

11 A. I remember having discussions with
12 Mark Steckel.

13 Q. Do you recall when your first
14 discussion was with Mr. Steckel?

15 A. No.

16 Q. Do you recall the circumstances of
17 your first discussion with Mark Steckel?

18 A. I recollect meeting with Mark Steckel
19 and discussing the invention.

20 Q. You met with him personally?

21 A. Yes.

22 Q. Was it at a meeting with other people
23 or just you and him?

24 A. I recollect meeting with him
25 individually.

1 GOODWIN

2 Q. Do you recall where?

3 A. I recollect meeting him at his office
4 location.

5 Q. Do you know where that is?

6 A. At the time, that would have been at
7 Ethicon.

8 Q. Is that in New Jersey?

9 A. Yes.

10 Q. So you went to his office to discuss
11 the invention?

12 A. That's what I recollect.

13 Q. I am sorry, you may have answered
14 this, do you recall if anybody else was there?

15 A. I don't believe anybody else was
16 there.

17 Q. The patent application filing date is
18 February 19, 1992. Do you see that?

19 A. Yes.

20 Q. Do you recall approximately how long
21 before the application was filed you met with
22 Mr. Steckel?

23 A. No.

24 Q. Can you rule out that it was a year
25 earlier?

EXHIBIT 22

DePuy Mitek's Privileged Document List
Civil Action No. 04-12457 PBS

January 25, 2006

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
1	09/20/02	Presentation			Attorney-Client	DMI001096A and DMI001098A: Redacted portions relate to legal advice concerning patent searches and results
2	11/21/03	Presentation			Attorney-Client	DMI001015A: Redacted portion relates to legal advice concerning patent searches and results
3	05/22/03	Presentation	George Cook		Attorney-Client	DMI001068A, DMI001070A, DMI001071: Redacted portions relate to legal advice concerning assessment of issued patents.
4	11/21/03	Presentation	Unknown		Attorney-Client	DMI001041A: Duplicate of privileged document #2
5	05/22/03	Presentation	George		Attorney-Client	DMI001083A, DMI001089, DMI001090A: Redacted portions relates to legal advice concerning issued patents
6	05/22/03	Presentation	George		Attorney-Client	DMI000981, DMI000984, DMI000992A: Redacted portions relate to legal advice concerning impact of issued patents
7	11/25/03	Presentation	McAlister Cook		Attorney-Client	DMI000973 and DMI000976: Redacted portions relate to legal advice concerning impact of issued patents
8	05/14/04	Report	Seppa		Attorney-Client	DMI000455: Redacted portion relates to legal advice concerning issued patents
9	09/23/97	Letter	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
10	10/20/97	Letter	Woodrow*	Groening*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
11	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
12	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
13	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
14	06/07/96	Letter	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
15	01/22/96	Letter	Woodrow*	Fritzsche*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
16	12/05/95	Letter	Fritzsche*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
17	07/08/93	Memo with notes	Clickner	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
18	07/22/02	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
19	07/17/01	Letter	Wissing*	Yasuda*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
20	07/17/01	Letter with notes	Wissing*	Yasuda*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
21	04/27/01	Letter	Yasuda*	Weiss*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
22	04/26/01	Letter	Yasuda*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
23	04/02/03	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
24	06/25/03	Letter	Yasuda*	Loo*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
25	06/13/03	Letter with notes	Loo*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
26	06/13/03	Email	Palko*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
27	06/11/03	Email	Loo*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
	06/11/03	Email	Loo*	Palko*	Attorney-Client	
28	06/11/03	Email	Loo*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
29	04/02/03	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
30	06/21/04	Report	Burkley	Seppa Howe	Attorney-Client/ Work Product	Communication seeking legal advice regarding patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
31	Undated	Draft Invention Disclosure	Koyfman Brucker Hill		Attorney-Client	Communication to counsel seeking legal advice concerning patentability of invention
32	07/15/04	Memo	Seppa	Skula* McAlister Leibowitz	Attorney-Client/ Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
33	08/19/04	Memo	Seppa	Skula* McAlister Leibowitz	Attorney-Client/ Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
34	02/18/04	Report	Seppa	Distribution	Attorney-Client/Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
35	11/25/03	Presentation	McAlister Cook		Attorney-Client	DMI006571: Redacted portion relates to legal advice concerning issued patents
36	11/08/02	Report	Longstreet	Ethicon GMB	Attorney-Client	DMI038171: Redacted portion relates to communication seeking legal advice concerning the patentability of an invention.
37	08/07/03	Plan			Attorney-Client	DMI039134: Redacted portion relates to reflecting legal advice concerning third party patent rights
38	Undated	Presentation			Attorney-Client	DMI0039239: Redacted portion relates to legal advice concerning Orthocord patent claims
39	Undated	Presentation			Attorney-Client	DMI39400: Redacted portion relates to request for legal advice concerning issued patents
40	09/02/03	Report	Koyfman Pokropinski		Attorney-Client	DMI039422: Redacted portion reflects legal advice concerning scope of issued patents
41	09/24/03	Report	Koyfman Pokropinski		Attorney-Client	DMI039447: Redacted portion reflects legal advice concerning scope of issued patents
42	11/04/02	Report	Dormier		Attorney-Client	DMI039473, DMI039474, DMI039475, DMI039486 and DMI039490: Redacted portions reflects legal advice concerning scope of issued patents
43	11/05/01	Report	Longstreet		Attorney-Client	DMI039496-97: Redacted portions reflects legal advice concerning scope of pending patent applications
44	02/27/03	Presentation			Attorney-Client	DMI039501, DMI039508 and DMI039513: Redacted portions reflect legal advice concerning issued patents and freedom to operate
45	09/02/04	Outline	Seppa		Attorney-Client/ Work Product	DMI039518: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
46	Undated	Notes			Attorney-Client	DMI039558: Redacted portion relates to reflects legal advice concerning issued patents

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
47	07/26/04	Outline			Attorney-Client/ Work Product	DMI039560: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
48	06/29/04	Outline			Attorney-Client/ Work Product	DMI039571: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
49	07/28/03	Report	Koyfman		Attorney-Client	DMI039621: Redacted portion reflects legal advice concerning issued patents
50	04/13/04	Presentation			Attorney-Client/ Work Product	DMI039675 and DMI039678: Redacted portion reflects legal advice concerning issued patents and pending patent application and reflects work performed at the direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
51	09/26/03	Report	Nozad		Attorney-Client	DMI039707: Redacted portion reflects request for legal advice concerning pending patent third party applications
52	Undated	Presentation			Attorney-Client	DMI039726 and DMI039747: Redacted portions relate legal advice concerning pending patent application and analysis of third party patent rights
53	Undated	Presentation			Attorney-Client	DMI039759: Redacted portions relate to legal advice concerning analysis of third party patent rights
54	5/27/04	Report	Seppa	Distribution	Attorney-Client/Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
55	Undated	Filed Application with handwritten notes	Matthew Goodwin*		Attorney Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
56	12/2/91	Letter	Matthew Goodwin*	M. Steckel	Attorney-Client	Communication reflecting legal advice concerning patent application
57	7/26/93	Letter	Dennis Jamiołkowski	Hal Woodrow* Donald Regina	Attorney-Client	Communication to counsel in furtherance of providing legal advice concerning response to Office Action from the USPTO
58	8/3/92	Letter	A. Hunter	Matthew Goodwin*	Attorney-Client	Communication to counsel in furtherance of providing legal advice concerning a response to an Office Action from the USPTO

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
59	12/20/91	Letter	Charles Fritz	Matthew Goodwin* M. Steckel	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
60	6/4/91	Letter	Matthew Goodwin*	M. Steckel	Attorney-Client	Communication from counsel reflecting legal advice concerning the patentability of invention
61	11/18/91	Letter	Mark Steckel	Matthew Goodwin* A. Finkenauf R. Lilienfeld B. Schwartz A. Skinner	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
62	7/14/92	Letter	Matthew Goodwin*	A. Hunter D. Jamiolkowski	Attorney-Client	Communication from counsel seeking information in connection with rendering legal advice concerning a response to an Office Action from the USPTO
63	11/20/92	Letter	A. Hunter	Matthew Goodwin*	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
64	11/13/92	Letter with handwritten comments	Matthew Goodwin*	Al Hunter Dennis Jamiolkowski	Attorney-Client	Communication from counsel in connection with providing legal advice concerning the patentability of invention and handwritten notes reflecting conversations concerning patentability of invention
65	11/15/93	Letter to File	Hal Woodrow*	File	Attorney-Client	Communication from counsel reflecting legal advice concerning analysis of Examiner's amendment and inventorship issues
66	Undated	Filed Application with handwritten notes	Hal Woodrow*		Attorney-Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
67	Undated	Filed Application with handwritten notes	Matthew Goodwin*		Attorney-Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
68	Undated	Letter to File	Hal Woodrow*	File	Attorney-Client	Communication from counsel reflecting legal advice concerning analysis of art cited abroad
69	1/8/90	Invention Disclosure Memorandum	Mark Steckel	Dr. C. Fritz Mr. A. Hunter Mr. D. Jamiolkowski Mr. D. Rembert Dr. B. Schwartz Dr. A. Skinner	Attorney-Client	Communication forwarded to counsel seeking legal advice concerning the patentability of invention

*=Attorney/Paralegal/Patent Agent

EXHIBIT 23

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
)	
)	
Plaintiff,)	
)	
vs.)	Case No. 04-12457 PBS
)	
Arthrex, Inc.,)	
)	
Defendant.)	

**ARTHREX, INC.'S ANSWER AND COUNTERCLAIM IN RESPONSE
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Arthrex, Inc. ("Arthrex") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

Parties, Jurisdiction and Venue

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.

3. Admitted.

4. Arthrex has insufficient information to admit or deny the allegations of paragraph 4 and therefore denies those allegations.

Answer to Depuy Mitek's Claim for Relief

5. Arthrex admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint,

and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page. Arthrex has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Arthrex denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Arthrex admits that it sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Arthrex denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Arthrex admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Arthrex denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Arthrex denies each and every allegation contained in paragraph 9 of the Amended Complaint.

10. Arthrex has insufficient information to admit or deny the allegations of paragraph 10 and therefore denies those allegations.

11. Arthrex denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Arthrex presents the following affirmative defenses:

AFFIRMATIVE DEFENSES

12. The '446 patent is invalid under 35 U.S.C. § 102.
13. The '446 patent is invalid under 35 U.S.C. § 103.
14. The '446 patent is invalid under 35 U.S.C. § 112.

15. Arthrex does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

16. Arthrex does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

17. By virtue of DePuy Mitek's unreasonable and unjustified delay in bringing the present lawsuit to the prejudice of Arthrex, recovery is barred under the doctrine of laches.

18. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

19. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

20. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a

suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

21. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

22. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenforced, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Arthrex.

COUNTERCLAIM

1. Arthrex, is a corporation organized under the laws of the State of Delaware, with its corporate headquarters and principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Arthrex repeats and realleges and incorporates herein by reference, paragraphs 12-22 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Arthrex and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 12-22 of Arthrex's Affirmative Defenses.

7. Arthrex seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Arthrex, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Arthrex and unenforceable, while asserting the patent against Arthrex, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Arthrex is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Arthrex prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Arthrex, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid

and unenforceable patent against Arthrex, with knowledge that Arthrex does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Arthrex under 35 U.S.C. § 285;

D. That the Court award Arthrex its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.

JURY DEMAND

Arthrex demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: September 26, 2005

Respectfully submitted,

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Counsel for Defendant
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Arthrex, Inc.'s Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was served via overnight courier on September 26, 2005, upon the following counsel for DePuy Mitek, Inc.:

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EXHIBIT 24

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.

Plaintiff,

vs.

Arthrex, Inc.,

Defendant.

Case No. 04-12457 PBS

**PEARSALLS LIMITED'S ANSWER AND COUNTERCLAIM IN RESPONSE
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Pearsalls Limited ("Pearsalls") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

Parties, Jurisdiction and Venue

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.

3. Admitted.

4. Admitted.

Answer to Depuy Mitek's Claim for Relief

5. Pearsalls admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint, and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page.

Pearsalls has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Pearsalls denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Pearsalls admits that Arthrex sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Pearsalls denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Pearsalls admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Pearsalls denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Pearsalls has insufficient information to admit or deny the allegations of the first sentence of paragraph 9 and therefore denies those allegations. Pearsalls denies the remaining allegations of paragraph 9.

10. Pearsalls admits the allegations of paragraph 10 of the Amended Complaint.

11. Pearsalls denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Pearsalls presents the following affirmative defenses:

AFFIRMATIVE DEFENSES

12. The Court lacks personal jurisdiction over Pearsalls since Pearsalls does not reside within this judicial district and DePuy Mitek has failed to allege that Pearsalls engages in business activity within this judicial district sufficient to vest this Court with personal jurisdiction over Pearsalls.

13. Service was insufficient because, upon information and belief, service of process was not performed in compliance with Rule 4(f) of the Federal Rules of Civil Procedure.

14. The '446 patent is invalid under 35 U.S.C. § 102.

15. The '446 patent is invalid under 35 U.S.C. § 103.

16. The '446 patent is invalid under 35 U.S.C. § 112.

17. Pearsalls does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

18. Pearsalls does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

19. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

20. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness

grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

21. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

22. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

23. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenforced, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Pearsalls.

COUNTERCLAIM

1. Pearsalls is a private limited company organized under the laws of the United Kingdom with a principal place of business at Tancred Street, Taunton, Somerset TA1 1RY.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Pearsalls repeats and realleges and incorporates herein by reference, paragraphs 12-23 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Pearsalls and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 14-23 of Pearsalls' Affirmative Defenses.

7. Pearsalls seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Pearsalls, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Pearsalls and unenforceable, while asserting the patent against Pearsalls, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Pearsalls is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Pearsalls prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Pearsalls, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid and unenforceable patent against Pearsalls, with knowledge that Pearsalls does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Pearsalls under 35 U.S.C. § 285;

D. That the Court award Pearsalls its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.

JURY DEMAND

Pearsalls demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: October 14, 2005

Respectfully submitted,

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Counsel for Defendants
Arthrex, Inc. and Pearsalls Limited

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Pearsalls Limited's Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was electronically filed with the Court and served via the Court's email notification service on October 14, 2005, upon the following counsel for DePuy Mitek, Inc.:

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Answers to Complaints

1:04-cv-12457-PBS DePuy Mitek, Inc. v. Arthrex, Inc.

United States District Court**District of Massachusetts**

Notice of Electronic Filing

The following transaction was received from Saber, Charles W. entered on 10/14/2005 at 4:00 PM EDT and filed on 10/14/2005

Case Name: DePuy Mitek, Inc. v. Arthrex, Inc.

Case Number: 1:04-cv-12457

Filer: Pearsalls Limited

Document Number: 20

Docket Text:

Pearsalls Limited's ANSWER to Amended Complaint *and*, COUNTERCLAIM against DePuy Mitek, Inc.(a Massachusetts Corporation) by Pearsalls Limited.(Saber, Charles)

The following document(s) are associated with this transaction:

Document description:Main Document

Original filename:yes

Electronic document Stamp:

[STAMP dcecfStamp_ID=1029851931 [Date=10/14/2005] [FileNumber=1163036-0] [8a594d78c391cb6b865e6211f1e32e2419c83c5474a104b052c598534355c780bd cfc8dfc163acf8ebbbce836697deeb08e48438d95c5e10cccede6f2019cba6]]

1:04-cv-12457 Notice will be electronically mailed to:

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EXHIBIT 25

US005147400A

United States Patent [19][11] **Patent Number:** **5,147,400****Kaplan et al.**[45] **Date of Patent:** **Sep. 15, 1992**[54] **CONNECTIVE TISSUE PROSTHESIS**[75] **Inventors:** Donald S. Kaplan, Weston; John Kennedy, Stratford; Ross R. Muth, Brookfield, all of Conn.[73] **Assignee:** United States Surgical Corporation, Norwalk, Conn.[21] **Appl. No.:** 581,462[22] **Filed:** Sep. 12, 1990**Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 349,648, May 10, 1989, Pat. No. 4,990,158.

[51] **Int. Cl.⁵** A61F 2/08[52] **U.S. Cl.** 623/13; 623/1; 623/11; 623/66[58] **Field of Search** 623/1, 13, 11[56] **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—David Isabella*Assistant Examiner*—Debra S. Brittingham*Attorney, Agent, or Firm*—Thomas R. Bremer; Peter G. Dilworth; Rocco S. Barrese

[57]

ABSTRACT

A semi-bioabsorbable connective tissue prosthesis, e.g., a replacement for the human anterior cruciate ligament, is provided whose stress-strain characteristics closely match those of the natural tissue.

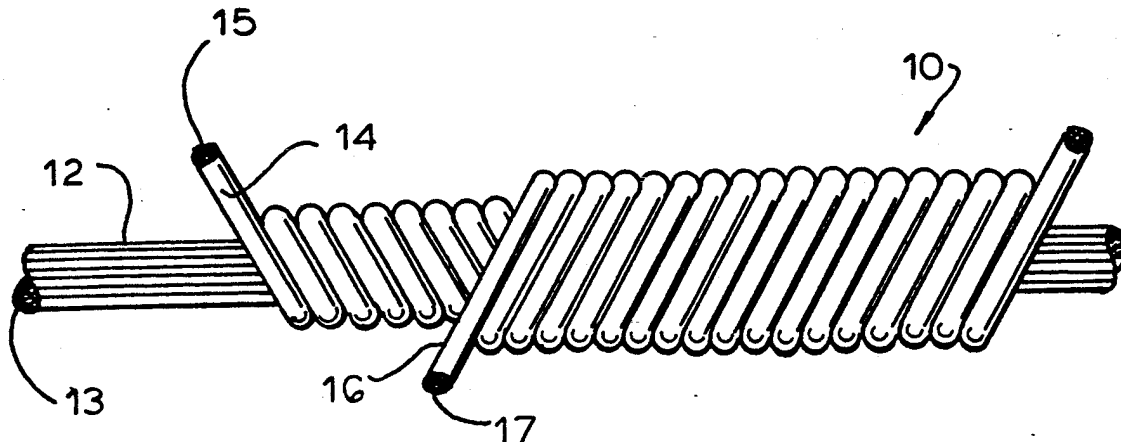
58 Claims, 5 Drawing Sheets

FIG. 1

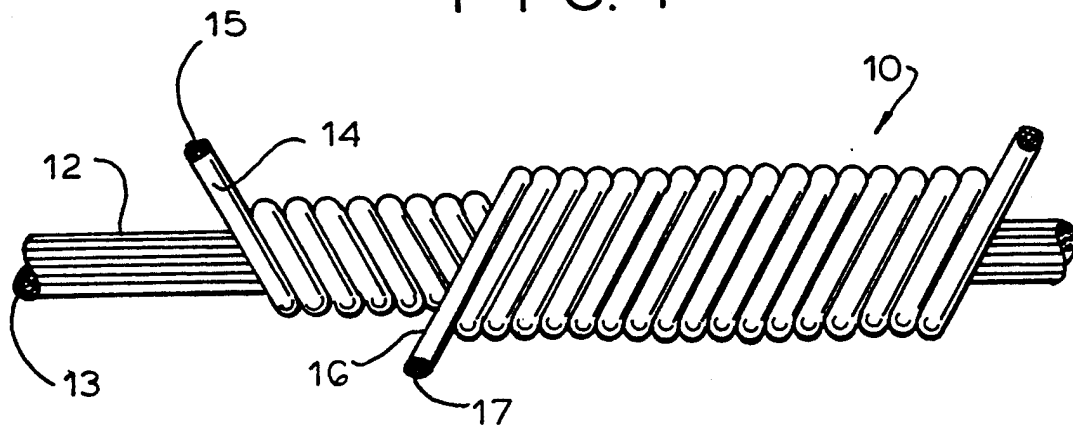


FIG. 2

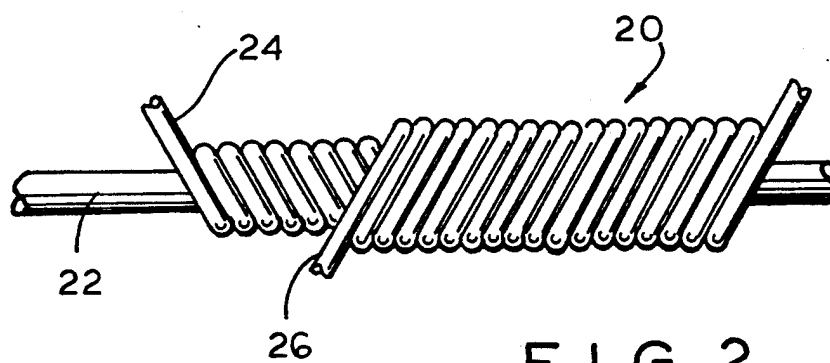


FIG. 5

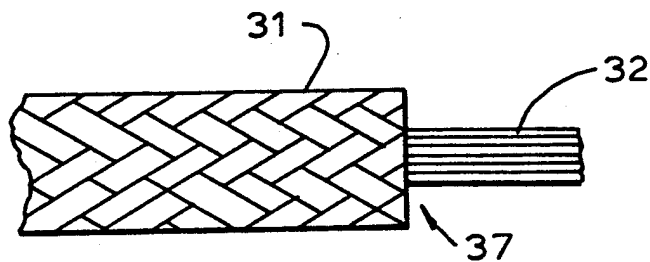


FIG. 3

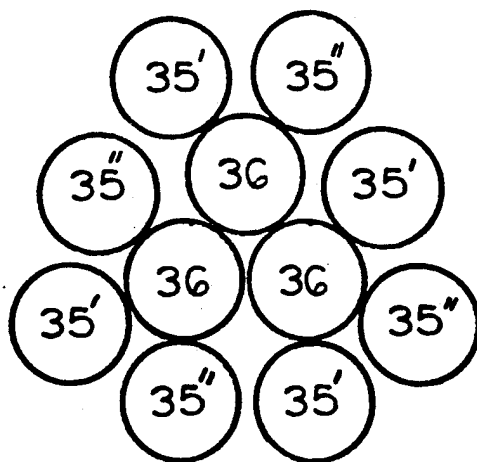
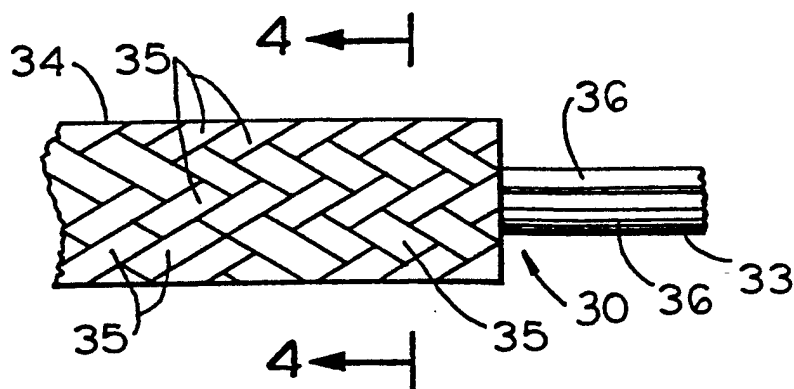


FIG. 4

FIG. 6

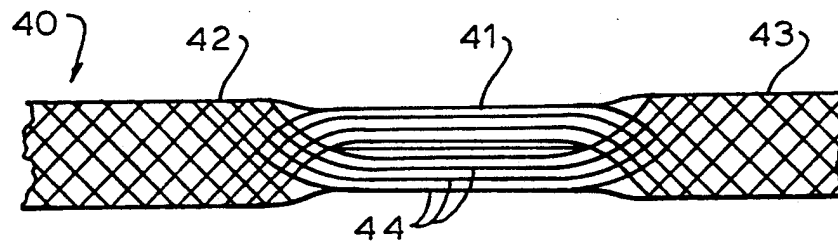
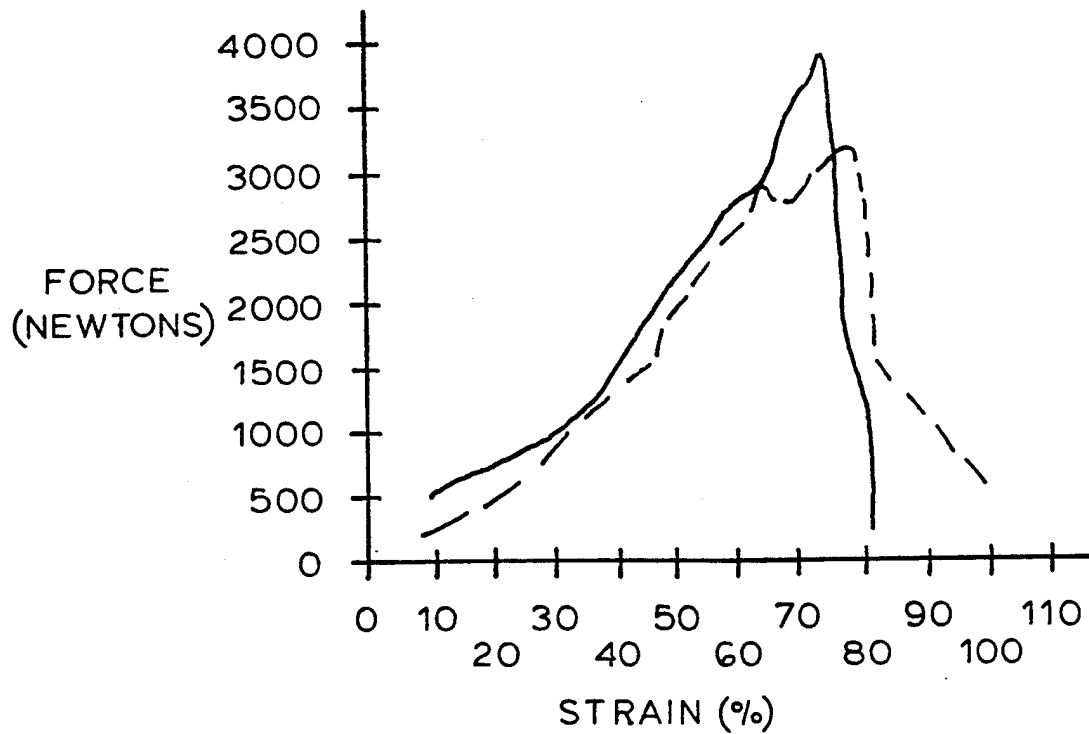


FIG. 7

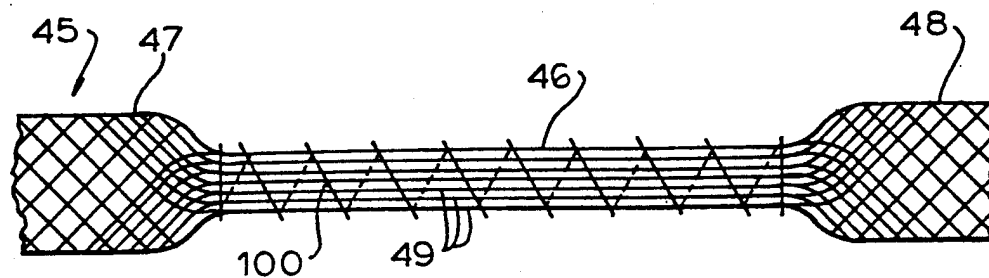


FIG. 8

FIG. 9

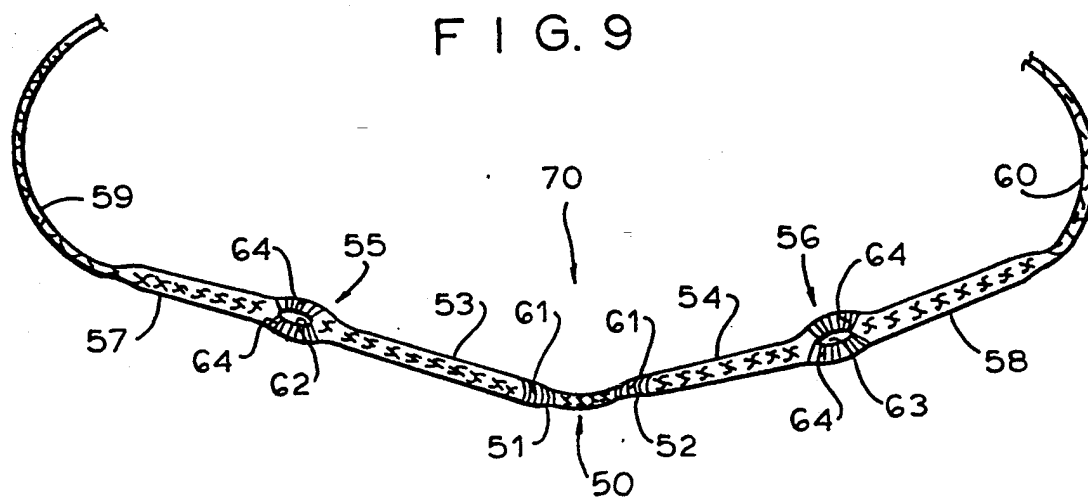


FIG. 10

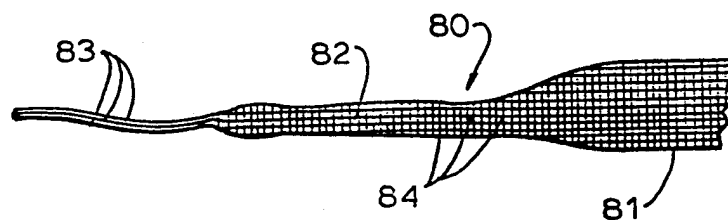


FIG. 11

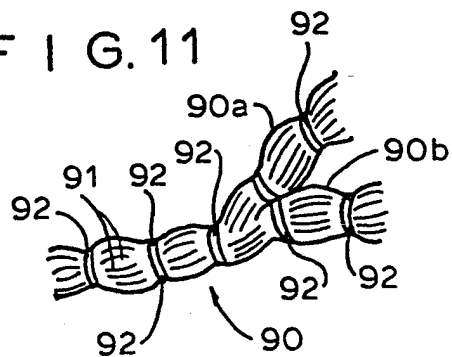
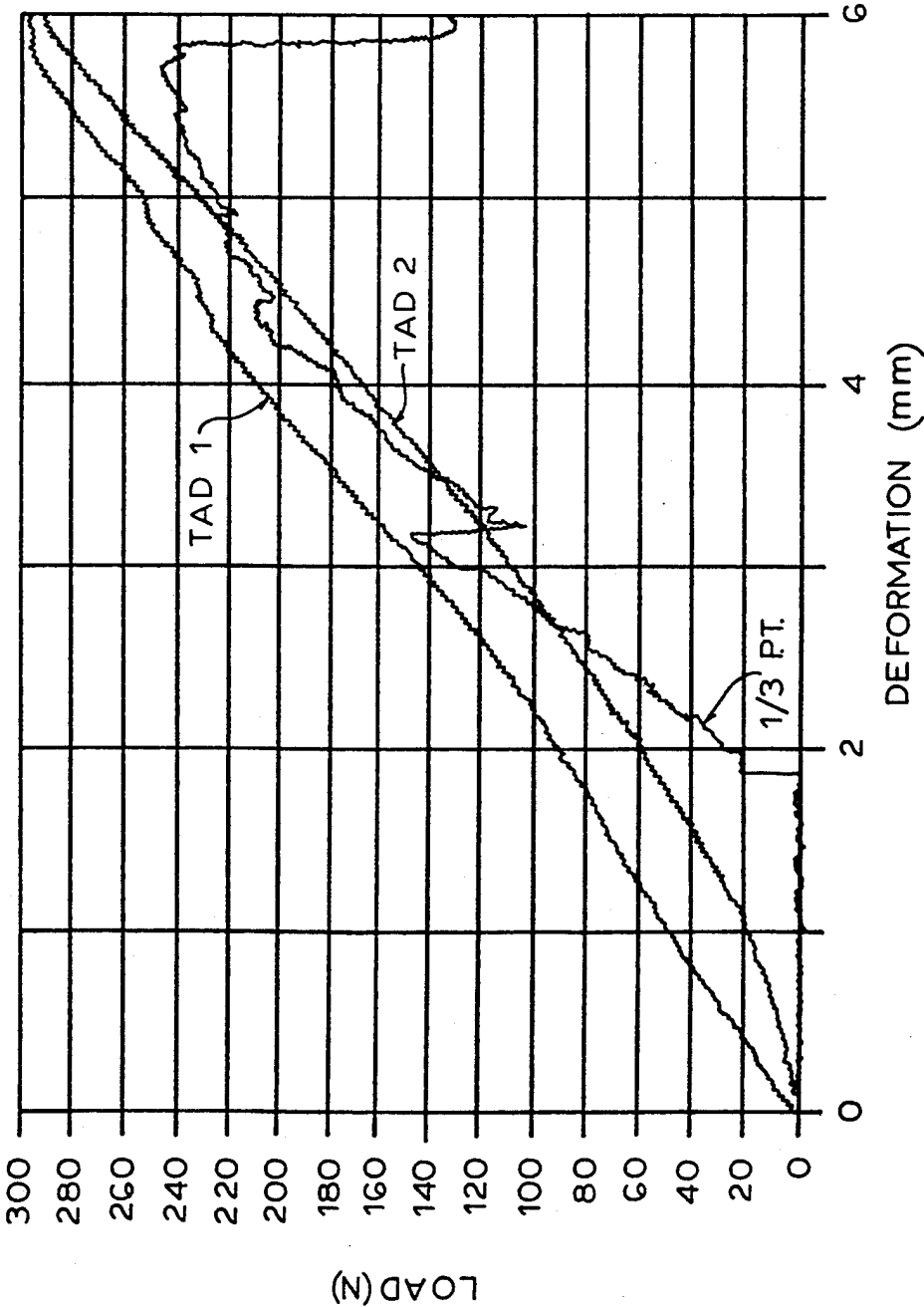


FIG. 12 TENSILE TESTS

100 % sec.



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CONNECTIVE TISSUE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

The application is a continuation-in-part of commonly assigned, co-pending U.S. patent application Ser. No. 349,648, filed May 10, 1989, now U.S. Pat. No. 4,990,158.

BACKGROUND OF THE INVENTION

This invention relates to a connective tissue prosthesis and, in particular, to a biocompatible ligament or tendon prosthesis which closely approximates the biomechanical characteristics of the natural tissue to be replaced or augmented.

Numerous connective tissue materials and constructions have been proposed for use as temporary or permanent grafts in ligament and tendon repair. Feagin, Jr., Ed., *The Crucial Ligaments/Diagnosis and Treatment of Ligamentous Injuries About the Knee* (Churchill Livingstone, N.Y., 1988) describes a number of partially bioabsorbable materials which have been investigated for use as ligament grafts. In Chapter 33 of this publication (Rodkey, "Laboratory Studies of Biodegradable materials for Cruciate Ligament Reconstruction"), it is reported that while a 100 percent biodegradable ligament fabricated from polyglycolic acid (PGA) was found to be safe, strong, well-tolerated and provided stability for the repaired anterior cruciate ligament in dogs, its complete resorption within five weeks makes it unsuitable for use in prostheses intended for humans since a human ligament prosthesis must provide support over a much longer period of time. It is further reported that a study in dogs of the intraarticular use of a partially biodegradable ligament prosthesis possessing a Dacron (i.e., DuPont's polyethylene terephthalate (PET)) and PGA core and a separate outer sleeve woven from PGA and Dacron of a different percentage of composition gave disappointing results.

U.S. Pat. Nos. 4,792,336 and 4,942,875 describe a surgical device for repairing or augmenting connective tissue and comprising a plurality of fibers, in which the majority of the fibers are in a direction essentially parallel to the length of the device and can be either 100 percent bioabsorbable or can contain a nonabsorbable component. Additionally, sleeve yarns consisting completely of absorbable material wrap around these axial or warp yarns.

Biomedical Business International Report No. 7041 (Second Revision, May 1986), "Orthopaedic and Diagnostic Devices", pages 5—5 to 5-12, identifies a variety of materials which have been used in the fabrication of prosthetic ligaments including carbon fiber, expanded Teflon (i.e., DuPont's polytetrafluoroethylene), a combination of silicone and PET, polypropylene, polyethylene, nickel-chromium alloy fibers individually enclosed in synthetic textile or natural silk, carbon material coated with gelatin, polyester combined with PET fibers, bovine tissues, and others.

Other disclosures of ligament and tendon repair devices are provided, inter alia, in U.S. Pat. Nos. 3,805,300; 4,187,558; 4,301,551; 4,483,023; 4,584,722; 4,610,688; 4,668,233; 4,775,380; 4,788,979; and PCT Patent Publication No. WO 89/01320.

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Chapter 33 (page 540) of the Feagin, Jr. publication referred to above identifies the characteristics of an ideal ligament prosthesis as follows:

- (1) it must be durable with adequate strength to withstand the extreme forces placed upon it, yet compliant enough to allow for repetitive motion without failure or excessive creep elongation;
- (2) it must be tolerated by the host with no antigenic or carcinogenic reaction;
- (3) if partially or completely biodegradable, the size of the individual fibers and the construction pattern must be appropriate to support and allow eventual reconstitution of the repaired structure with ingrowth of fibrous tissue that matures to normal or near normal collagen;
- (4) it must tolerate sterilization and storage; and
- (5) it should be easily implanted using surgical and potentially arthroscopic techniques.

The existence of so many different types of materials and devices for use in connective tissue repair, some of which have been identified above, bears testimony to the difficulty of meeting some, much less all, of the foregoing characteristics in a single prosthetic device.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a semi-bioabsorbable or fully bioabsorbable connective tissue prosthesis, e.g., a ligament or tendon repair device, which exhibits the stress-strain properties of the natural tissue to be replaced or augmented.

It is a specific object of the invention to provide the foregoing connective tissue prosthesis as a structure formed from a composite yarn comprising a non-bioabsorbable core yarn surrounded by a bioabsorbable or semi-bioabsorbable cover or sheath yarn.

It is a further specific object of the invention to provide a connective tissue prosthesis formed from a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-bioabsorbable sheath yarn, so as to exhibit the stress-strain properties of natural tissue.

It is another specific object of the invention to provide a prosthetic replacement for a human anterior cruciate ligament which is based on the aforesaid structure, in particular, one fabricated from a yarn whose sheath yarn component is derived from a glycolide-lactide copolymer.

In keeping with these and other objects of the invention, there is provided a connective tissue prosthesis comprising:

- (a) a core made up of a first biocompatible composite yarn extending in the lengthwise direction; and
 - (b) a sheath surrounding the core and fabricated from a second biocompatible yarn,
- wherein the first composite yarn in the core (a) comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The second biocompatible yarn forming the sheath (b) may be the same as, or different from, the first composite yarn which forms the core (a). More specifically, the second biocompatible yarn may also comprise a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

Also in keeping with the above and other objects of the invention, a connective tissue prosthesis is provided which comprises a tubular component fabricated from

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composite yarn, the yarn comprising a biocompatible, nonbioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The foregoing connective tissue prostheses meet the Feagin, Jr. criteria, identified supra, to a surprising degree. Due to elasticity of the composite yarn core component and relative inelasticity of the composite yarn sheath component, the stress-strain characteristics of the connective tissue prostheses closely match those of the natural tissue which they replace and their resorption properties can be calibrated to maintain the functionality of the prostheses throughout the entire period of the tissue regeneration process. The prostheses of this invention are readily sterilizable, possess good storage stability when suitably protected from hydrolytic forces, and can be installed at a ligament, tendon, vascular, or tracheal repair site employing known surgical reconstruction techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are enlarged isometric views of composite yarns which are utilized in the construction of the connective tissue prosthesis herein;

FIG. 3 is an enlarged isometric view of an alternative composite yarn utilized in the construction of the connective tissue prosthesis herein;

FIG. 4 is a schematic, cross-sectional view along line 4-4 of FIG. 3;

FIG. 5 represents a section of a ligament prosthesis manufactured from the composite yarn of FIG. 1 and suitable for use in the surgical reconstruction of the human anterior cruciate ligament;

FIG. 6 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 5 compared with the stress-strain characteristics of a natural ligament as reported in the literature;

FIG. 7 represents a section of a tubular ligament prosthesis manufactured from the composite yarn of the present invention and having an unbraided center section;

FIG. 8 represents a section of a tubular ligament prosthesis similar to FIG. 7 and additionally having the unbraided center section helically wrapped with a yarn;

FIG. 9 represents a section of a braided prosthesis manufactured from composite yarn of the present invention and modified in various fashion over the length thereof;

FIG. 10 represents a section of a tubular braided prosthesis manufactured from composite yarn of the present invention and provided with threading means;

FIG. 11 represents a section of a prosthesis manufactured from composite yarn of the present invention in which the prosthesis is branched; and

FIG. 12 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 7 compared with a canine patellar tendon.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, composite yarn 10 comprises a core yarn component 12 made up of a multiplicity of individual biocompatible, essentially non-bioabsorbable and preferably elastic filaments 13, advantageously provided with a slight to moderate twist, and a sheath yarn component 14 made up of a multiplicity of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 15 wound in a

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first direction around the core and an external multifilamentous sheath yarn component 16, also made up of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 17, wound in a second and opposite direction around sheath yarn component 14. For example, multifilamentous sheath yarn component 16 may comprise both absorbable and non-absorbable filaments 17. Generally, the filaments 13 of core yarn component 12 are substantially parallel.

Non-bioabsorbable core yarn component 12 functions to impart elasticity to composite yarn 10 and acts as a scaffolding during and after absorption of the bioabsorbable sheath. Bioabsorbable sheath yarn components 14 and 16 function to provide the composite yarn with relative inelasticity, tensile strength, and absorption characteristics which allow for desirable tissue ingrowth and incorporation of the composite yarn into the body structure. Sheath yarn components 14 and 16 each have a lengthwise axis which is non-perpendicular to the lengthwise axis of core component 12. While core yarn component 12 can be wrapped with a single layer of sheath yarn component, the illustrated arrangement of two layers of sheath yarn components 14 and 16 is generally preferred as this construction helps to give composite yarn 10 a balanced structure which resists crimping or kinking when used in the manufacture of a prosthesis such as shown in FIGS. 5 and 7-11.

Where, as shown in the embodiment of FIG. 1, at least two sheath yarn components are employed in the construction of the composite yarn, the composition, number and denier of the individual filaments, and braiding (if any) of these yarn components as well as their relative rates of bioabsorption can differ. For example, non-absorbable filaments may be combined with absorbable filaments to provide one or more semi-absorbable sheath yarn components. This capability for differential absorption can be advantageously exploited in a connective tissue prosthetic device in which the outermost sheath yarn component is absorbed by the body at a faster rate than the underlying sheath yarn component, or vice versa. thus resulting in a staged absorption of the sheath components of the composite yarn.

Core yarn component 12 must be essentially non-bioabsorbable, i.e., it must resist degradation when, as part of the connective tissue prosthesis of this invention, it is implanted in a body. The term "non-bioabsorbable" as used herein applies to materials which permanently remain within the body or at least remain in the body for a relatively long period of time, e.g., at least about two years. It is preferred to employ a core yarn material which is also elastic, i.e., a polymeric material which in filamentous form exhibits a relatively high degree of reversible extensibility, e.g., an elongation at break of at least about 30 percent, preferably at least about 40 percent and more preferably at least about 50 percent. Fiber-forming polymers which are both non-bioabsorbable and elastic, and as such preferred for use as the core yarn component herein, include fiber-forming polyolefins such as polyethylene homopolymers, polypropylene homopolymers, ethylene propylene copolymers, ethylene propylene terpolymers, etc., fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, polyether-polyester copolymers, and the like. Hytrel (DuPont), a family of copolyester elastomers based on (soft) polyether segments and (hard) polyester segments, and span-

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dex, an elastomeric segmented polyurethane, provide especially good results.

Hytrel is manufactured in various commercial grades by DuPont, such as Hytrel 4056, 5526, 5556 and 7246. Hytrel 5556 is especially suitable as the core component 12 of the composite yarn 10 when used to form a vascular graft, while Hytrel 7246 is well-suited for the core component 12 of the composite yarn 10 when used to form a ligament prosthesis or tendon augmentation device.

Several properties of the various Hytrel grades are presented in the table below:

	Hytrel Grade No. (Injection Molded at 23° C. for Testing)			
	4056	5526	5556	7246
Hardness in durometer points (ASTM Test No. D2240)	40	55	55	72
Flexural Modulus (ASTM Test No. D790)				
at -40° C. in MPa	155	930	930	2,410
at -40° F. in psi	22,500	135,000	135,000	350,000
at 23° C. in MPa	55	207	207	518
at 73° F. in psi	8,000	30,000	30,000	75,000
at 100° C. in MPa	27	110	110	207
at 212° F. in psi	3,900	16,000	16,000	30,000
ASTM Test No. D638				
(i) Tensile Strength at Break,				
MPa	28.0	40.0	40.0	45.8
psi	4050	5800	5800	6650
(ii) Elongation at Break, %	550	500	500	350
(iii) Tensile Stress at 5% Strain,				
MPa	2.4	6.9	6.9	14.0
psi	350	1,000	1,000	2,025
(iv) Tensile Stress at 10% Strain,				
Mpa	3.6	10.3	10.3	20.0
psi	525	1,500	1,500	2,900
Izod Impact (Notched) (ASTM Test No. D256, Method A)				
at -40° C. in J/cm	No Break	No Break	No Break	0.4
at -40° F. in ft-lbf/in	No Break	No Break	No Break	0.8
at 23° C. in J/cm	No Break	No Break	No Break	2.1
at 73° F. in ft-lbf/in.	No Break	No Break	No Break	3.9
Resistance to Flex Cut Growth, Ross (Pierced), in Cycles to 100% cut growth (ASTM. Test No. D1052)	>1 × 10 ⁶	>5 × 10 ⁵	>5 × 10 ⁵	—
(iii) Initial Tear Resistance, Die C (ASTM Test No. D1004),				
in kN/m	101	158	158	200
in lbf/in.	580	900	900	1,146
Melt Flow Rate in g/10 min. (ASTM Test No. D1238)	5.3	18	7.0	12.5
Test Conditions: Temperature, °C./Load, Kg	190/2.16	220/2.16	220/2.16	240/2.16
(iv) Melting Point (ASTM Test No. D3418)				
in °C.	148	202	202	219
in °F.	298	396	396	426
Vicat Softening Point (ASTM Test No. D1525)				
in °C.	108	180	180	207
in °F.	226	356	356	405
Specific Gravity (ASTM Test No. D792)	1.16	1.20	1.20	1.25
Water Absorption, 24 hr. in % (ASTM Test No. D570)	0.6	0.5	0.5	0.3

(i) head speed 50 mm/min. or 2 in/min.

(ii) head speed 25 mm/min. or 1 in/min.

(iii) specimens 1.9 mm or 0.075 in. thick.

(iv) differential scanning calorimeter (DSC), peak of endotherm

Corresponding properties of other grades of Hytrel are available from DuPont.

If desired, the core yarn component can be provided with a nonabsorbable hydrophilic coating to improve its wettability by body fluids, e.g., synovial fluid. Hy-

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drophilic coatings which are suitable for this purpose include polymeric materials such as the sparingly cross-linked poly(hydroxyethyl methacrylate) hydrogels disclosed in U.S. Pat. Nos. 2,976,576 and 3,220,960; hydrogels based on cross-linked polymers of n-vinyl lactams and alkyl acrylates as disclosed in U.S. Pat. No. 3,532,679; graft copolymers of hydroxyalkyl methacrylate and polyvinylpyrrolidone disclosed in U.S. Pat. No. 3,621,079, and many others.

10 Fiber-forming materials which are relatively inelastic are suitable for providing the sheath yarn component of composite yarn 10 provided such materials are fairly

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rapidly bioabsorbed by the body, e.g., exhibiting a loss of tensile strength in from about 2 to about 26 weeks and total absorption within from about two to about fifty

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two weeks. It is to be understood, however, that the expression "relatively inelastic" does not preclude the presence of some minor degree of elasticity in the sheath yarn component, merely that it excludes a degree of elastic behavior as described in connection with the preferred type of core yarn component.

The sheath yarn component can be woven, braided or knitted in whole or in part and will ordinarily possess a relatively high tensile strength, e.g., a straight tensile strength of at least about 30,000 p.s.i., preferably at least about 60,000 p.s.i. and more preferably at least about 90,000 p.s.i.

Bioabsorbable, relatively inelastic fiber-forming polymers and polymer blends from which the sheath yarn component herein can be formed include those derived at least in part from such monomers as glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ε-caprolactone, hydroxycaproic acid, etc., and various combinations of these and related monomers as disclosed, e.g., in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,052,988; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; 4,429,080; 4,441,496; 4,523,591; 4,546,152; 4,559,945; 4,643,191; 4,646,741; 4,653,497; and, 4,741,337; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolide/poly(lactic acid) homo- and copolymers: 1", *Polymer*, Volume 20, pages 1459–1464 (1979), and D. F. Williams (ed.), *Biocompatibility of Clinical Implant Materials*, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

Sheath yarn components manufactured from polymers of high lactide or glycolide content, e.g., those in which at least about 75 percent of the monomeric units are derived from either glycolide or lactide, are preferred for the construction of the composite yarn of this invention. Polymers of high glycolide content tend to be absorbed more quickly than those possessing a high lactide content. Accordingly, the glycolide-based polymers may be preferred for the manufacture of a sheath yarn component providing the outermost sheath yarn(s) in a multiple sheath yarn component construction, the underlying internal sheath yarn(s) being manufactured from the more slowly absorbable lactide-based polymers. An especially preferred lactide-glycolide copolymer for forming the sheath yarn component of the composite yarn contains from about 70 to about 90, and preferably from about 75 to about 85 mole percent lactide monomer with the balance being provided by the glycolide monomer. Thus, for example, a sheath yarn component formed from a lactide-glycolide copolymer based on 80 mole percent lactide-20 mole percent glycolide is especially advantageous for constructing the composite yarn, and ultimately, the connective tissue prosthesis, of the present invention. The sheath yarn component, which is preferably braided around the core yarn component, may comprise a plurality of bioabsorbable fibers in turn comprising at least two different chemical compositions.

The deniers of core yarn component 12 and sheath yarn components 14 and 16 are not especially critical and those of commercially available yarns such as Vicryl (a glycolide/lactide copolymer suture available from Ethicon) and Dexon (a polyglycolide suture available from American Cyanamid) are suitably employed.

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Preferably, the deniers are selected so as to provide a composite yarn having an overall denier of from about 40 to about 1200 and preferably from about 80 to about 500, the overall denier of the core and/or sheath yarn components being from about 20 to about 600 and preferably from about 40 to about 300. The deniers of individual filaments in the core and sheath yarn components of multifilamentous construction can vary widely, e.g., from about 0.2 to about 6.0 and preferably from about 0.4 to about 3.0. The base weight for a desired composite yarn will determine the size and weight of the component elements of the yarn. Composite yarn 10 possesses sufficient core material to impart, inter alia, a desired resiliency and sufficient sheath material to provide, inter alia, a desired tensile strength for a particular connective tissue prosthetic application. In general, the core component can represent from about 20 to about 80 percent, and preferably from about 30 to about 70 percent of the total weight of composite yarn 10. Optimum core and sheath component weights will naturally vary depending on the specific application and can be readily determined in a given case based on the desired physical properties of the prosthetic device without undue experimentation.

Methods and apparatus for covering core yarn components with sheath yarn components are well known and need not be described here in detail. In general, the sheath yarn components are wrapped about the core yarn component on a covering machine which includes a hollow spindle with rotating yarn supply bobbins supported thereon. The elastic core yarn component is fed through the hollow spindle and the elastic sheath yarn components are withdrawn from the alternate direction rotating supply bobbins and wrapped about the core yarn component as it emerges from the hollow spindle. The core yarn component is preferably under a slight tension during the covering procedure and the sheath yarn components are laid down in a side-by-side array. The number of wraps per inch will depend on the denier of the sheath yarn components but should be sufficient to cause the sheath yarn components to lay close to the core yarn component when tension on the latter is relaxed.

As desired, the filaments which comprise a sheath yarn component can be provided with no twist or with varying degrees of twist. Where the yarns are twisted, it can be advantageous to balance or equalize the twist in the final composite yarn structure. Thus, for example, in the embodiment of composite yarn 10 in FIG. 1, if sheath yarn component 14 has a given twist, sheath yarn component 16 should have an equivalent twist. Since sheath yarn components 14 and 16 are laid down in opposite directions, the twist in each of these yarn components will be neutralized in the final structure of the composite yarn. Similarly, sheath yarn components 14 and 16 are advantageously of about equal weight in order to provide further balance in the composite yarn.

The composite yarn 20 shown in FIG. 2 is similar to that of FIG. 1 except that core yarn component 22 constitutes a monofilament and internal and external sheath yarn components 24 and 26, respectively, each constitutes a monofilament. In all other structural and compositional respects, composite yarn 20 can be like that of composite yarn 10.

An alternative composite yarn 30 is illustrated in FIGS. 3 and 4. Composite yarn 30 comprises a core yarn component 33 and a braided sheath yarn component 34. As with core yarn components 12 and 22 of

FIGS. 1 and 2, core yarn component 33 is made up of one or more biocompatible, essentially non-bioabsorbable and preferably elastic filaments 36 which define the longitudinal axis of composite yarn 30. Braided sheath yarn component 34 comprises individual sheath yarn filaments or sheath yarn filament bundles 35 which traverse core yarn component 33 in a substantially conventional braided configuration to provide core yarn component 33 with a braided tubular external sheath 34. The individual sheath yarn filaments or sheath yarn filament bundles 35 are biocompatible, bioabsorbable or semi-bioabsorbable, and relatively inelastic. In a preferred embodiment of the present invention as illustrated in FIGS. 3 and 4, sheath yarn component 34 comprises sheath yarn filaments of different chemical composition. For example, a portion of the sheath yarn filaments 35', e.g., 30 to 70% by weight, may be formed of a bioabsorbable polymer exhibiting relatively slow bioabsorption, e.g., polylactide or a copolymer comprising a high lactide mole percentage, while the remainder of the sheath yarn filaments 35'' may be formed of a second bioabsorbable polymer which exhibits relatively fast bioabsorption, e.g., polyglycolide or a copolymer comprising a high glycolide mole percentage. Sheath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable.

In the embodiment illustrated in FIGS. 3 and 4, core yarn component 33 is preferably manufactured from Hytrel filaments 36 and has a denier of about 270, while sheath yarn component 34, which is braided on an eight carrier braider, has a denier of about 204, for a total denier of this composite yarn 30 of about 474.

FIG. 5 illustrates an anterior cruciate ligament prosthesis 37 manufactured from warp and filling composite yarns 10 of FIG. 1. Prosthesis 37 is constructed by constructing a sheath 31 about core 32 by weaving, braiding or knitting on a known or conventional loom. For example, the sheath may be braided about the core on a braiding machine which includes braider bobbins. Composite yarn forming the sheath may be wound onto an appropriate number of braider bobbins which are then loaded onto a carrier braider with the yarns on the bobbins then being braided and tied to form the sheath. The core (if one is required) can be pulled through the sheath, e.g. manually to form the prosthesis. In other words, the core will be at least partially surrounded by the sheath. Other prostheses illustrated herein can be manufactured in similar fashion. The sheath components of the individual composite yarns from which ligament prosthesis 30 is manufactured will erode over time due to their bioabsorption leaving only the nonabsorbable core component as a permanent or long term scaffold for new ligament tissue growth.

FIGS. 7-11 illustrate examples of other ligament prostheses which can be manufactured from the composite yarn of the present invention, e.g. as illustrated in FIGS. 1-3. More particularly, FIG. 7 illustrates a tubular ligament prosthesis or tendon augmentation device 40 having an unbraided center section 41 bounded by braided sections 42 and 43. The individual composite yarns 44 in the unbraided center section 41 can be drawn in generally parallel relationship, if required. The length of the unbraided center section 41 can vary, e.g., from about one or two inches up to about seven or eight inches. The unbraided center section 41 provides tensile strength and/or tissue ingrowth advantages.

Additionally, a tubular ligament prosthesis or tendon augmentation device 45 as illustrated in FIG. 8 can be manufactured from the composite yarn of the present invention. The prosthesis 45 is similar to the one illustrated in FIG. 7 and comprises an unbraided center section 46 bounded by braided sections 47 and 48. A helical wrap 100 is provided about the unbraided center section 46 to improve handling and manipulation of the unbraided section 46 during implantation, while absorption/degradation of the helical wrap 100 frees the individual yarns 49 of the center unbraided section 46 to provide the appropriate tensile strength and/or tissue ingrowth advantages. In this regard, the yarn forming the helical wrap 100 can be the composite yarn of FIGS. 1-3 or formed of a different kind of material, e.g. completely bioabsorbable or nonbioabsorbable material. The tubular ligament prostheses of FIGS. 7 and 8 are both constructed by braiding the end sections 42, 43 or 47, 48 in a known or conventional loom and, in the case of FIG. 8, additionally wrapping the helical yarn 100 about the center unbraided section 46, also with a known or conventional loom. The prostheses of FIGS. 7 and 8 are especially suitable as replacements for anterior cruciate ligaments.

FIG. 9 illustrates a braided prosthesis 70 which can be manufactured from the composite yarns of FIGS. 1-3 and which is also modified along the length thereof. More specifically, the prosthesis of FIG. 9 comprises a center region 50 bordered by first outer regions 51, 52, second outer regions 53, 54, third outer regions 55, 56, fourth outer regions 57, 58, and fifth outer regions 59, 60. The center region 50 comprises a sheath of braided composite yarn, e.g., as illustrated in FIGS. 1-3, about a core (not illustrated) also formed of composite yarn. First outer regions 51, 52 additionally comprise a wrapping 61 about the braided yarn, this wrapping 61 being formed of the same composite yarn as illustrated in FIGS. 1-3 or a different kind of material, e.g. a totally bioabsorbable or nonabsorbable material. This wrapping 61 serves to at least temporarily retain the sheath about the core.

The second outer regions 53, 54 also formed of tubular braided composite yarn as illustrated in FIGS. 1-3 with an appropriate core material (not illustrated) that forms a thicker core than any core present in center section 50 (the center section 50 can be coreless, if required). Third outer regions 55, 56 are divided as illustrated in FIG. 9 to form respective openings 62 and 63. This allows attachment means to be inserted through the respective openings to secure the ligament prosthesis 70 in place. As illustrated in FIG. 9, the sections 55, 56 around the openings 62 and 63 are also covered with wrapping 64 which is similar to the wrapping 61 covering regions 51 and 52.

Next, fourth outer regions 57 and 58 follow which are similar in structure and composition to second outer regions 53 and 54. Regions 57 and 58 narrow down into fifth outer regions 59 and 60 as illustrated in FIG. 9, which can be used, e.g. for threading the ligament prosthesis 70. All sections of prosthesis 70, including the various wrappings 61 and 64, can be fabricated together on a conventional known loom. Prosthesis 70 is especially suitable as a replacement for an anterior cruciate ligament.

FIG. 10 discloses a coreless prosthetic ligament 80 that can be prepared from the composite yarn illustrated in FIGS. 1-3. The coreless prosthetic ligament is braided with a wider central section 81, and a narrower

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outer section from which unwoven yarns 83 extend to form a leading section to enhance threading of prosthetic ligament 80 upon implantation. Sheath yarns 84 of prosthetic ligament 80 can be woven, braided, or knitted on a conventional loom. Sheath sections 81 and 82 of ligament prostheses 80 are tubular, i.e. coreless. Prostheses 80 is also especially suitable as a replacement for an anterior cruciate ligament.

As illustrated in FIG. 11, a ligament prosthesis 90 can be prepared from composite yarns illustrated in Figs. 1-3 of the present invention which form a sheath about a supporting structure (not illustrated). This supporting structure can be a core formed from the composite yarns as described above, or it can be a single, integral member, formed of semi-bioabsorbable or non-bioabsorbable material forming a supporting base for yarns 91. This supporting structure, along with the bundle of yarns 91, can be divided into two branches 90a and 90b, with the yarns 91 of the prosthesis retained on the supporting structure or core at various points by fastening means 92 which can also be constituted by composite yarn of FIGS. 1-3 or by other kinds of material, e.g. totally bioabsorbable or nonabsorbable filaments. In this regard, the yarns 91 need just be bundled together without any interweaving, braiding or knitting, so long as the yarns 91 are securely held together on the core by the fastening means 92. Alternatively, yarns 92 can be woven, knitted, or braided about the core on a conventional loom to form branches 90a and 90b.

Other prosthetic structures which can be prepared with the composite yarn of the present invention are apparent to one of skill in the art in light of the disclosure herein.

It is within the scope of this invention to coat or impregnate the prosthesis with, or otherwise apply thereto, one or more materials which enhance its functionality, e.g., surgically useful substances, such as those which accelerate or beneficially modify the healing process when the prosthesis is applied to a graft site. So, for example, the prosthesis can be provided with a therapeutic agent which will be deposited at the grafted site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting tissue repair or for specific indications such as thrombosis. Thus, for example, antimicrobial agents such as broad spectrum antibiotics (gentamicin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be incorporated into the prosthesis to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site.

To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the tubular prosthesis, e.g., fibroblast growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. To decrease abrasion, increase lubricity, etc., the prosthesis can be coated with copolymers of glycolide and lactide and polyethylene oxide, calcium salts such as calcium stearate, compounds of the Pluronic class, copolymers of caprolactone, caprolactone with PEO, polyHEMA, etc. Especially advantageous is a coating of hyaluronic acid with or without cross-linking.

Additionally, polypeptides such as Human Growth Factor (HGF) can also be coated upon or impregnated in the prosthesis to promote healing. The term "Human Growth Factor" or "HGF" embraces those materials, known in the literature, which are referred to as such

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and includes their biologically active, closely related derivatives. The HGFs can be derived from naturally occurring sources and are preferably produced by recombinant DNA techniques. Specifically, any of the HGFs which are mitogenically active and as such effective in stimulating, accelerating, potentiating or otherwise enhancing the wound healing process are useful herein, e.g., hEGF (urogastrone), TGF-beta, IGF, PDGF, FGF, etc. These and other useful HGFs and closely related HGF derivatives, methods by which they can be obtained and methods and compositions featuring the use of HGFs to enhance wound healing are variously disclosed, inter alia, in U.S. Pat. Nos. 3,883,497; 3,917,824; 3,948,875; 4,338,397; 4,418,691; 4,528,186; 4,621,052; 4,743,679 and 4,717,717; European Patent Applications 0 046 039; 0 128 733; 0 131 868; 0 136 490; 0 147 178; 0 150 572; 0 177 915 and 0 267 015; PCT International Applications WO 83/04030; WO 85/00369; WO 85/01284 and WO 86/02271 and UK Patent Applications GB 2 092 155 A; 2,162,851 A and GB 2 172 890 A, all of which are incorporated by reference herein. Of the known HGFs, hEGF, TGF-beta and IGF are preferred for use in the therapeutic composition of this invention.

The HGFs can be introduced with appropriate carrier such as carrier proteins disclosed, e.g., in "Carrier Protein-Based Delivery of Protein Pharmaceuticals", a paper of Biogrowth, Inc., Richmond, Calif., presented at a symposium held June 12-14, 1989 in Boston, Mass.

EXAMPLE 1

The following illustrates the manufacture of a ligament prosthesis as illustrated in FIG. 5.

A 420 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn as the core component and a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn providing the sheath component.

Six plies of the 420 denier composite yarn were wound onto 32 braider bobbins. The bobbins were loaded onto a 32 carrier braider to provide braided sheath 31. About one meter of the yarns from the 32 bobbins was pulled manually in parallel to provide a core 32 of 80,640 (420×6×32) overall denier. Application of braided sheath 31 also 420×6×32 or 80,640 overall denier resulted in ligament prosthesis 37 possessing an overall denier of 161,280. The stress (force in Newtons)-strain characteristics of prosthesis 37 were measured and compared with the stress-strain characteristics of a human anterior cruciate ligament as reported in Noyes et al., *Journal of Bone and Joint Surgery*, Vol. 58-A, No. 8, p. 1074, et seq. (Dec. 1976). As shown in the plotted data of FIG. 6, the stress-strain characteristics of prosthesis 37 (continuous line) closely matched those of the natural tissue (broken line), an altogether remarkable achievement relative to known connective tissue prostheses.

EXAMPLE 2

The following illustrates manufacture of a tendon augmentation device 40 as illustrated in FIG. 7.

A 431 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn to provide the core component 12, a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn to provide the inner sheath component 14, and a lactide (10 mole percent)-glycolide (90 mole percent) copolymer yarn to provide the outer sheath component 16.

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Six plies of the 431 denier composite yarn were wound onto 16 braider bobbins. The bobbins were loaded onto a 16 carrier braider to provide braided sections 42 and 43. About 70 mm of the yarn from the 16 braider bobbins was braided to form one of sections 42 and 43, and then the braiding was stopped. Then, about 35 mm. of the yarn from the 16 braider bobbins was pulled manually to form the unbraided center section 41, and then braiding was continued for another 70 mm of the yarn to form the other of sections 42 and 43. The resulting tendon augmentation device 40 had a total denier of 41,376 ($431 \times 6 \times 16$).

The tendon augmentation device 40 was implanted in a canine knee replacing the center third of the patellar tendon. Physical testing was carried out comparing two tendon augmentation devices 40 (TAD-1 and TAD-2) to the center third of the canine patellar tendon ($\frac{1}{3}$ P.T.) being replaced. More specifically, the stress (force in Newtons) —strain or load-deformation characteristics of devices 40 and the canine patellar tendon were measured and compared with one another.

As shown in the plotted data of FIG. 12, the responses of both tendon augmentation devices 40 (TAD 1 and TAD 2) were very similar to the one third canine patellar tendon. Moreover, tendon augmentation devices 40 (TAD 1 and TAD 2) were generally stronger than the replaced canine patellar tendon which failed when too great a load was applied thereto.

EXAMPLE 3

A composite yarn as illustrated in FIGS. 3 and 4 was fabricated using Hytrel 7246 fibers as the core component 33 and bioabsorbable sheath component fibers 35 of two different chemical compositions: first bioabsorbable fibers 35' fabricated from an 80 mole percent lactide/20 mole percent glycolide copolymer, and second bioabsorbable fibers 35'' fabricated from a 10 mole percent lactide/90 mole percent glycolide copolymer. The first bioabsorbable fibers 35' were formed into yarn bundles, each yarn bundle comprising 12 filaments and having a total denier of 24. The second bioabsorbable fibers 35'' were also formed into yarn bundles, each yarn bundle comprising 17 filaments and having a total denier of 27.

The composite yarn was formed using three Hytrel yarn bundles, each Hytrel yarn bundle comprising 70 filaments, to form a core component 33 of approximately 270 denier. The braided sheath component 34 was formed around the Hytrel core component 33 using an 8 carrier braider, 4 carriers each of the first and second bioabsorbable yarn bundles. The composite yarn thus formed exhibited a tensile strength of 3.19 grams/denier, and is suitable for use in fabricating a connective tissue prosthesis of the present invention.

What is claimed is:

1. A connective tissue prosthesis comprising:
 - a) a core made up of a first biocompatible composite yarn extending in a lengthwise direction; and
 - b) a sheath surrounding the core, said sheath being fabricated from a second biocompatible yarn; the first composite yarn in said core (a) comprising a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.
2. The connective tissue prosthesis of claim 1, wherein the second biocompatible yarn in said sheath (b) comprises a non-bioabsorbable core yarn component

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surrounded by an at least semi-bioabsorbable sheath yarn component.

3. The connective tissue prosthesis of claim 2 wherein the sheath yarn component is bioabsorbable.

4. The connective tissue prosthesis of claim 1 exhibiting stress-strain characteristics approximately those of the natural connective tissue replaced or augmented by the prosthesis.

5. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a ligament or tendon prosthesis.

6. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a human anterior cruciate ligament prosthesis.

7. The connective tissue prosthesis of claim 1 in which the core component comprises at least one filament.

8. The connective tissue prosthesis of claim 7 in which the core (a) of the prosthesis comprises multiple composite yarns.

9. The connective tissue prosthesis of claim 7 wherein the core component comprises multiple filaments.

10. The connective tissue prosthesis of claim 1 in which the sheath component comprises at least one filament.

11. The connective tissue prosthesis of claim 10 wherein the sheath yarn component comprises multiple filaments.

12. The connective tissue prosthesis of claim 1 in which the core component is manufactured from at least one polymeric material selected from the group consisting of polyethylene homopolymers, polypropylene homopolymers, ethylene-propylene copolymers, ethylene propylene terpolymers, fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, and polyether-polyester copolymers.

13. The connective tissue prosthesis of claim 1 in which the core component possesses an elongation at break of at least about 30 percent.

14. The connective tissue prosthesis of claim 1 in which the sheath component is an absorbable, relatively inelastic polymeric material derived at least in part from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ϵ -caprolactone and hydroxycaproic acid.

15. The connective tissue prosthesis of claim 1 in which the sheath component is a lactide-glycolide copolymer.

16. The connective tissue prosthesis of claim 12 in which the sheath component is a lactide-glycolide copolymer containing from about 70 to about 90 mole percent lactide units.

17. The connective tissue prosthesis of claim 16 in which the sheath component is a lactide-glycolide copolymer containing from about 75 to about 85 mole percent lactide units.

18. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially woven.

19. The connective tissue prosthesis of claim 18 wherein the sheath (b) is entirely woven.

20. The connective tissue prosthesis of claim 1 further comprising at least one bioactive substance.

21. The connective tissue prosthesis of claim 1, wherein said sheath component is helically wound about said core component.

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22. The connective tissue prosthesis of claim 21, additionally comprising

a second sheath component helically wound about said sheath component in a different direction.

23. The connective tissue prosthesis of claim 22, in which said second sheath component is a lactide-glycolide copolymer.

24. The connective tissue prosthesis of claim 22, wherein said first and second sheath components have different ratios of absorption.

25. The connective tissue prosthesis of claim 1, wherein said sheath component is braided around said core component.

26. The connective tissue prosthesis of claim 25, wherein said sheath component comprises a plurality of bioabsorbable fibers, said fibers comprising at least two different chemical compositions.

27. The connective tissue prosthesis of claim 1, wherein said core (a) and sheath (b) together are branched at discrete locations to form gaps between branches of said prosthesis.

28. The connective tissue prosthesis of claim 27, wherein a yarn is wrapped about said sheath (b) at discrete locations to at least temporarily retain said sheath (b) about said core (a).

29. The connective tissue prosthesis of claim 28, wherein said wrapping yarn comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a at least semi-bioabsorbable sheath yarn component.

30. The connective tissue prosthesis of claim 29 wherein said sheath component of said wrapping yarn is bioabsorbable.

31. The connective tissue prosthesis of claim 1 wherein said sheath yarn component is bioabsorbable.

32. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially braided.

33. The connective tissue prosthesis of claim 32 wherein the sheath (b) is entirely braided.

34. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially knitted.

35. The connective tissue prosthesis of claim 34 wherein the sheath (b) is entirely knitted.

36. A connective tissue prosthesis comprising:

a tubular component fabricated from composite yarn, said yarn comprising a biocompatible, core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

37. The connective tissue prosthesis of claim 36, comprising a center section where said yarn is unbraided and bordered by sections where said yarn is braided.

38. The connective tissue prosthesis of claim 37, additionally comprising

a helical wrap about said unbraided center section.

39. The connective tissue prosthesis of claim 38, wherein said helical wrap is fabricated from composite yarn comprising a biocompatible, non-bioabsorbable

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core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

40. The connective tissue prosthesis of claim 39, wherein said sheath component is bioabsorbable.

41. The connective tissue prosthesis of claim 36, additionally comprising

a threading member attached to an end thereof, said threading member comprising a composite yarn which comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

42. The connective tissue prosthesis of claim 41 wherein said sheath component is bioabsorbable.

43. The connective tissue prosthesis of claim 36 wherein said sheath component is bioabsorbable.

44. Method for manufacturing a connective tissue prosthesis, comprising

forming said connective tissue prosthesis from a first biocompatible composite yarn comprising a non-bioabsorbable core yarn component surrounded by an at least semibioabsorbable sheath yarn component.

45. The method of claim 44, wherein said connective tissue prosthesis comprises a core and a sheath, said core being at least partially surrounded by said sheath.

46. The method of claim 45, wherein said biocompatible composite yarn forms said core.

47. The method of claim 44, wherein said biocompatible composite yarn forms said sheath.

48. The method of claim 44, wherein the sheath is woven about the core.

49. The method of claim 48, wherein the sheath is braided from braider bobbins loaded onto a carrier braider, and the core is pulled through the thus-braided sheath.

50. The method of claim 48 wherein the sheath is braided about the core.

51. The method of claim 44 wherein said sheath component is bioabsorbable.

52. The method of claim 44 wherein the sheath is knitted about the core.

53. Method for manufacturing a tubular connective tissue prosthesis, comprising

forming a tubular component from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

54. The method of claim 53 wherein the tubular component is formed by weaving.

55. The method of claim 53 wherein the tubular component is formed by braiding.

56. The method of claim 55, wherein the tubular component is braided from braider bobbins loaded onto a carrier braider.

57. The method of claim 53 wherein the tubular component is formed by knitting.

58. The method of claim 53 wherein the sheath component is bioabsorbable.

* * * * *

EXHIBIT 26

Deposition of:
Hal Brent Woodrow

November 2, 2005

Page 1

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2

UNITED STATES DISTRICT COURT

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DISTRICT OF MASSACHUSETTS

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C.A. No. 04-12457 PBS

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ORIGINAL

6

DePUY MITEK, INC.,

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a Massachusetts corporation,

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Plaintiffs,

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v.

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ARTHREX, INC.

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a Delaware Corporation,

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Defendant.

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DEPOSITION OF HAL BRENT WOODROW

17

New Brunswick, New Jersey

18

November 2, 2005

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Reported by:

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MARY F. BOWMAN, RPR, CRR

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JOB NO. 97

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Deposition of:
Hal Brent Woodrow

November 2, 2005

Page 159

1 WOODROW

2 place they talk about how to make their
3 semibioabsorbable sheath.

4 Q. Show me in the Kaplan reference where
5 you are referring to where it is --

6 A. It is column 9, 25 through --

7 Q. What's the Bates number, I am sorry.

8 A. DMI 225.

9 Q. Where are you?

10 A. That's columns 9, lines 25 through 28.
11 When read in context with the rest of the
12 specification, this is the only place that I found
13 that they discuss how to make semibioabsorbable
14 sheath.

15 Q. So column 9, line 25 through 28 is
16 describing what?

17 A. Their semibioabsorbable sheath.

18 Q. Where does it say that?

19 A. Going to the summary of the invention,
20 which is DMI 221, reading at lines 33, talking
21 about the prosthesis, they are talking about it
22 made from a composite yarn comprising a
23 nonbioabsorbable core yarn surrounded by
24 bioabsorbable or semibioabsorbable cover or sheath
25 yarn.

EXHIBIT 27



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.
 Serial No.: 838,511 Art Unit: 1504
 Filed : February 19, 1992 Examiner: C. Raimund
 For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
 (Date of Deposit)

Hal B. Woodrow
 Name of applicant, assignee, or Registered Representative

Hal B. Woodrow
 (Signature)

August 3, 1993
 (Date of Signature)

Hon. Commissioner of Patents
 and Trademarks
 Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

IN THE CLAIMS

Please amend claim 2/ as follows:

(Once Amended)

CM 1. A surgical suture [comprising] consisting essentially of
 a [the] heterogeneous braid [of claim 1] composed of a first and
second set of continuous and discrete yarns in a sterilized,
braided construction wherein at least one yarn from the first set
is in direct intertwining contact with a yarn from the second set;
 and

PI a) each yarn from the first set is composed of a plurality of
filaments of a first fiber-forming material selected from the group
consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

PI b) each yarn from the second set is composed of a plurality of
filaments of a second fiber-forming material selected from the
group consisting of PET, nylon and aramid; and

PI c) optionally a core.

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CLAIM 2

DePuy Mitek, Inc. v. Arthrex, Inc.
 C.A. No.04-12457 PBS
 DMI000258

REMARKS

4. Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amended to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting of PET, nylon and aramid materials. Support for these amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddie et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddie is a significant contribution to the art, Doddie does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32,501

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One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995